

The Birmingham Rehabilitation Uptake Maximisation Study (BRUM). Home-based compared with hospital-based cardiac rehabilitation in a multi-ethnic population: cost-effectiveness and patient adherence

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and A Stevens



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Abstract

The Birmingham Rehabilitation Uptake Maximisation Study (BRUM). Home-based compared with hospital-based cardiac rehabilitation in a multi-ethnic population: cost-effectiveness and patient adherence

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Objectives: To evaluate the relative effectiveness and cost-effectiveness of a home-based programme of cardiac rehabilitation using the Heart Manual, with centre-based programmes. It also sought to explore the reasons for non-adherence to cardiac rehabilitation programmes.

Design: An individually randomised trial, with minimisation for age, gender, ethnicity, initial diagnosis and hospital of recruitment. Participants were followed up after 6, 12 and 24 months by questionnaire and clinical assessment. Individual semistructured interviews were undertaken in the homes of a purposive sample of patients who did not adhere to their allocated programme, and focus groups were undertaken with groups of patients who adhered to the programmes.

Setting: Four hospitals in predominantly inner-city, multi-ethnic, socio-economically deprived areas of the West Midlands in England, for 2 years from 1 February 2002.

Participants: A total of 525 patients who had experienced a myocardial infarction (MI) or coronary revascularisation within the previous 12 weeks.

Interventions: All the rehabilitation programmes included exercise, relaxation, education and lifestyle counselling. All patients were seen by a cardiac rehabilitation nurse prior to hospital discharge and provided with information about their condition and counselling about risk factor modification. The four centre-based programmes varied in length from nine

sessions at weekly intervals of education, relaxation and circuit training to 24 individualised sessions over 12 weeks of mainly walking, fixed cycling and rowing with group-based education. The home-based programme consisted of an appropriate version of the Heart Manual, home visits and telephone contact. The Heart Manual was introduced to patients on an individual basis, either in hospital or on a home visit. Home visits by a nurse took place at approximately 1, 6 and 12 weeks after recruitment, with a telephone call at 3 weeks. At the final visit, patients were encouraged to maintain their lifestyle changes and to continue with their exercise programme. Where needed, follow-up was made by a rehabilitation nurse who spoke Punjabi. An audiotape of an abridged version of the Heart Manual in Punjabi accompanied the manual for patients with a limited command of English.

Main outcome measures: Primary outcomes were smoking cessation, blood pressure, total and high-density lipoprotein cholesterol, exercise capacity measured by the incremental shuttle walking test and psychological status measured by the Hospital Anxiety and Depression Scale (HADS). Secondary outcomes included self-reported diet, physical activity, cardiac symptoms and quality of life. Health service resource use and costs of rehabilitation programmes from health service and societal perspectives were also measured. Adherence to the physical activity element of the rehabilitation programmes was measured by questionnaire 6, 9 and 12 weeks.

Results: No clinically or statistically significant differences were found in any of the primary or secondary outcome measures between the home- and centre-based groups. Significant improvements in total cholesterol, smoking prevalence, the HADS anxiety score, self-reported physical activity and diet were seen in both arms between baseline and the 6-month follow-up. Five or more contacts with a cardiac rehabilitation nurse were received by 96% of home-based participants, whereas only 56% of centre-based participants attended this many rehabilitation classes. The direct rehabilitation costs to the health service were significantly higher for the home-based programme (mean cost £198 versus £157 for the centre-based programme), but when patient costs were included the mean cost of the centre-based arm rose to £182. Patients' reasons for not taking up or adhering to cardiac rehabilitation were multifactorial and very individual. Other health problems limited some patients' ability to exercise. Most non-adherers found some aspects of their cardiac rehabilitation programme helpful. Many had adapted advice on rehabilitation and were continuing to exercise in other ways and had made lifestyle changes, particularly to their diet. The home-based patients' lack of motivation to exercise on their own at home was a major factor in non-adherence. The focus groups revealed little

diversity of views among patients from each programme. Patients in the hospital programme enjoyed the camaraderie of group exercise and the home-based patients valued the wealth of information and advice in the Heart Manual.

Conclusions: A home-based cardiac rehabilitation programme for low- to moderate-risk patients does not produce inferior outcomes compared with the traditional centre-based programmes. With the level of home visiting in this trial, the home-based programme was more costly to the health service, but with the difference in costs borne by patients attending centre-based programmes. Different reasons were given by home and hospital cardiac rehabilitation patients for not taking up or adhering to cardiac rehabilitation, with home-based patients often citing a lack of motivation to exercise at home. Social characteristics, individual patient needs and the location of cardiac rehabilitation programmes need to be taken into account in programme design to maximise participation. Research is recommended into cardiac rehabilitation in patients from ethnic minority groups; measurement tools to assess physical activity and dietary change; evaluating the Heart Manual in patients who decline centre-based cardiac rehabilitation; the implementation of home-based programmes in the UK; and strategies that sustain physical activity in the long term.



Contents

List of abbreviations	vii	Interactions and subgroup analysis	35
Executive summary	ix	Two-year study outcomes	35
1 Background	1	Repeated measures analysis of primary outcomes	37
The impact of ischaemic heart disease	1	Centre effect	37
What is cardiac rehabilitation?	1	Health service resource use	43
Effectiveness of cardiac rehabilitation	1	Economic analysis	43
Guidelines for cardiac rehabilitation provision	2	4 Results of qualitative studies	51
Provision of cardiac rehabilitation in the UK	3	Individual interviews with non-adherers ...	51
Models of cardiac rehabilitation	3	Focus groups of adherers	65
Uptake and adherence	3	Interviews with Punjabi-speaking participants	72
Need for alternative models of cardiac rehabilitation to improve uptake and adherence	5	5 Discussion	73
Economic and costing studies	6	Health outcomes	73
Aims and objectives of the study	6	Adherence	75
2 Methods	9	Internal validity	75
The study population	9	Generalisability	76
Setting	9	Ethnic minority issues	77
Study design	9	Qualitative study findings	78
Allocation to trial group	10	Economic study findings	80
Content of interventions	10	Conclusions	81
Training of nurses	12	Relevance of findings to the NHS	82
Outcome measures	12	Recommendations for research	83
Sample size	14	Acknowledgements	85
Analysis	14	References	87
Qualitative studies	16	Appendix 1 Dietary questionnaire	95
Economic study	17	Appendix 2 Unit costs to be used in CHD treatment model, England 2000–1	97
Changes to the project protocol	18	Health Technology Assessment reports published to date	99
3 Quantitative results	19	Health Technology Assessment Programme	115
Recruitment and baseline details	19		
Uptake and adherence data	19		
Crossovers	21		
Six-month study outcomes	21		
Twelve-month study outcomes	28		



List of abbreviations

ACE	angiotensin-converting enzyme	ISWT	incremental shuttle walking test
ANOVA	analysis of variance	ITT	intention-to-treat
BMI	body mass index	MCS	mental component score (of the SF-12)
BRUM	Birmingham Rehabilitation Uptake Maximisation	MI	myocardial infarction
CABG	coronary artery bypass graft	PCS	physical component score (of the SF-12)
CHD	coronary heart disease	PTCA	percutaneous transluminal coronary angioplasty
CI	confidence interval	QALY	quality-adjusted life-year
CR	cardiac rehabilitation	RCT	randomised controlled trial
DBP	diastolic blood pressure	RR	relative risk
DNA	did not attend	SBP	systolic blood pressure
ECG	electrocardiogram	SD	standard deviation
EQ-5D	EuroQol quality of life questionnaire	SF-12	Short Form with 12 Items
GMS	Global Mood Score	SIGN	Scottish Intercollegiate Guidelines Network
HADS	Hospital Anxiety and Depression Scale	SPSS	Statistical Package for Social Sciences
HDL	high-density lipoprotein	TC	total cholesterol
IMD	Index of Multiple Deprivation		

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.



Executive summary

Objectives

The study aimed to evaluate the relative effectiveness and cost-effectiveness of a home-based programme of cardiac rehabilitation using the Heart Manual, with centre-based programmes in patients who have experienced a myocardial infarction (MI) or coronary revascularisation within the previous 12 weeks. In addition, it sought to explore the reasons for non-adherence to cardiac rehabilitation programmes.

Methods

Design

This was an individually randomised trial, with minimisation for age, gender, ethnicity, initial diagnosis and hospital of recruitment. Participants were followed up after 6, 12 and 24 months by questionnaire and clinical assessment. Individual semistructured interviews were undertaken in the homes of a purposive sample of patients who did not adhere to their allocated programme, and focus groups were undertaken with groups of patients who adhered to the programmes.

Setting and patients

Recruitment took place of patients referred to cardiac rehabilitation teams at four hospitals in predominantly inner-city, multi-ethnic, socio-economically deprived areas of the West Midlands, for 2 years from 1 February 2002. Patients were excluded if they were deemed as too high risk for a home-exercise programme, which included patients with unstable angina, clinically significant heart failure, important cardiac arrhythmias or significant lesions remaining post-angioplasty or bypass. Of the 1997 patients presenting with the index events, 1207 (60%) were eligible for the study and 525 (43% of eligible patients) were recruited, with 263 randomised to the home-based arm and 262 to the centre-based arm. Interviews were undertaken with 49 participants who were 'non-adherers' and five focus groups were run for adhering participants.

Intervention

All the rehabilitation programmes included exercise, relaxation, education and lifestyle

counselling. All patients were seen by a cardiac rehabilitation nurse prior to hospital discharge and provided with information about their condition and counselling about risk factor modification.

The four centre-based programmes varied in length from nine sessions at weekly intervals of education, relaxation and circuit training to 24 individualised sessions over 12 weeks of mainly walking, fixed cycling and rowing with group-based education.

The home-based programme consisted of a manual, home visits and telephone contact. Patients who had had an MI were discharged home with *The Heart Manual* (second edition). Those who had had a revascularisation received an adapted version of the Heart Manual for this patient group. The Heart Manual was introduced to patients on an individual basis, either in hospital or on a home visit. Home visits by a nurse took place at approximately 1, 6 and 12 weeks after recruitment, with a telephone call at 3 weeks. At the final visit, patients were encouraged to maintain their lifestyle changes and to continue with their exercise programme. Patients who had an insufficient command of English were followed up by a rehabilitation nurse who spoke Punjabi. An audiotape of an abridged version of the Heart Manual in Punjabi accompanied the manual for patients with a limited command of English.

Main outcome measures

Primary outcomes were smoking cessation, blood pressure, total and high-density lipoprotein cholesterol, exercise capacity measured by the incremental shuttle walking test and psychological status measured by the Hospital Anxiety and Depression Scale (HADS). Secondary outcomes included self-reported diet, physical activity, cardiac symptoms and quality of life. Health service resource use and costs of rehabilitation programmes from health service and societal perspectives were also measured. Adherence to the physical activity element of the rehabilitation programmes was measured by questionnaire at 6, 9 and 12 weeks.

Results

At all three follow-up points no clinically or statistically significant differences were found in any of the primary outcome measures between the home- and centre-based groups or in any of the secondary outcomes.

Significant improvements in total cholesterol, smoking prevalence, the HADS anxiety score, self-reported physical activity and diet were seen in both the home- and centre-based arms between baseline and the 6-month follow-up.

Five or more contacts with a cardiac rehabilitation nurse were received by 96% of participants in the home-based arm, whereas only 56% of participants in the centre-based arm attended this many rehabilitation classes ($p < 0.001$).

The direct rehabilitation costs to the health service were significantly higher for the home-based programme; the mean cost was £198 [95% confidence interval (CI) £189 to £208] versus £157 (95% CI £139 to £175), $p < 0.05$, for the centre-based programme. When patient costs were included, the mean cost of the centre-based arm rose to £182 (difference not significant). The programme at Hospital 1 had a significantly higher mean cost than that for Hospital 2 or Hospitals 3 and 4 combined.

Patients' reasons for not taking up or adhering to cardiac rehabilitation were multifactorial and very individual. Other health problems, such as arthritis, and continuing cardiac problems limited some patients' ability to exercise. The majority of non-adherers found some aspects of their cardiac rehabilitation programme helpful. Many had adapted advice on rehabilitation and were continuing to exercise in other ways and had made lifestyle changes, particularly to their diet. On the home-based programme, patients' lack of motivation to exercise on their own at home was a major factor in non-adherence.

The focus groups revealed little diversity of views among patients from each programme. In particular, patients in the hospital programme

enjoyed the camaraderie of group exercise and the home-based patients valued the wealth of information and advice in the Heart Manual.

Conclusions

For low- to moderate-risk patients following MI, percutaneous transluminal coronary angioplasty or coronary artery bypass graft, a home-based cardiac rehabilitation programme does not produce inferior outcomes compared with the traditional centre-based programmes. With the level of home visiting in this trial, the home-based programme was more costly to the health service, but with the difference in costs borne by patients attending centre-based programmes.

Reasons for non-participation/non-adherence were multifactorial and individualistic, with in most cases one critical factor that determined eventual cardiac rehabilitation behaviour. There were differences in the reasons given by home and hospital cardiac rehabilitation patients, with home-based patients often citing a lack of motivation to exercise at home. Social characteristics, individual patient needs and the location of cardiac rehabilitation programmes need to be taken into account in programme design to maximise participation

Recommendations for further research

Research is recommended in the following areas:

- cardiac rehabilitation in patients from ethnic minority groups
- development of measurement tools to assess physical activity and dietary change and translated and validated tools in minority languages for these and to measure psychological status
- evaluation of the Heart Manual in patients who decline centre-based cardiac rehabilitation
- evaluation of the implementation of home-based programmes in the UK
- evaluation of strategies that sustain physical activity in the long term.

Chapter I

Background

The impact of ischaemic heart disease

Cardiovascular disease accounts for one-third of deaths globally, with 7.22 million deaths from coronary heart disease (CHD) in 2002.¹ In Europe, CHD is the most common cause of death and in the UK it accounts for one in five deaths in men and one in six deaths in women.^{2,3} Although the mortality rate from CHD has been falling in the UK, principally due to a reduction in risk factors, particularly smoking, it has fallen less than in many other developed countries.³ Treatments to individuals, including secondary prevention, explain about 42% of the decline in CHD mortality in the 1980s and 1990s.⁴ South Asians living in the UK have a higher premature death rate from CHD than average and their mortality rate from CHD has fallen by less than for the UK as a whole.³

What is cardiac rehabilitation?

Cardiac rehabilitation (CR) services aim to facilitate physical, psychological and emotional recovery and to enable patients to achieve and maintain better health.⁵ This is achieved through exercise, patient education and advice, relaxation, drug therapy and specific help for patients with psychological sequelae.^{6–8} CR is delivered by a multidisciplinary team, and in the UK it usually comprises four phases, each phase delivering advice and support appropriate to the stage of the patient's recovery and aiming to help the patient achieve optimal physical and psychological health.⁹

Phase I of CR takes place in hospital and consists of education about the patient's disease, advice about their likely recovery and a plan of activities suitable for after their discharge. Phase II is the time between discharge from hospital and attending a supervised rehabilitation programme. Some patients will receive a home visit or telephone call to monitor progress and provide support. Others use educational materials provided by the rehabilitation staff. Phase III is generally a supervised programme of outpatient-based CR, lasting approximately 8 weeks and

delivered by a multidisciplinary rehabilitation team. Key elements of the programme are supervised exercise, education about lifestyle changes to reduce cardiac risk factors, advice about medication, psychological support and monitoring of the patient's recovery. The final Phase IV involves the maintenance of the lifestyle changes and physical activity encouraged in Phase III. This may be provided in the form of a maintenance exercise programme in the community or a cardiac support group.

Effectiveness of cardiac rehabilitation

The effectiveness of exercise-based CR following myocardial infarction (MI) has been evaluated by a large number of randomised controlled trials (RCTs) and several systematic reviews.^{10–14} These all report a lower all-cause mortality and death rate from cardiovascular causes in the arms who received CR rather than usual care. The reviews differ in which groups found statistically significant reductions in mortality. Details of the reviews are summarised in *Table 1*.

The effectiveness of psychological interventions has been addressed in a recent review.¹⁵ This found no effect on total or cardiac mortality for psychological or stress management interventions. A combined analysis of all the psychological and stress management trials found a reduction in non-fatal MI, but the largest trials did not show this outcome and there was evidence of significant publication bias. Previous reviews have reported a reduction in mortality,^{16–18} but were not fully systematic in their coverage and did not differentiate the different psychosocial and stress management interventions.¹⁵

Effectiveness of cardiac rehabilitation post-revascularisation

The number of participants in trials of comprehensive and exercise-based CR post-revascularisation is less than that of post-MI patients, but the beneficial effect of CR is consistent across different diagnostic groups (MI and revascularisation).¹³

TABLE 1 Summary of reviews of the effectiveness of exercise-based cardiac rehabilitation compared with usual care

Review	Population	Results	Comments
Oldridge, 1988 ¹¹	4347 patients in 10 trials All post-MI Only 2.9% women Aged <71 years	All-cause mortality: OR 0.76, 95% CI 0.63 to 0.92 Cardiovascular mortality: OR 0.75, 95% CI 0.62 to 0.93 No reduction in non-fatal MI	Trials were pre-thrombolysis treatment and use of many secondary preventive medications. Limited by selected nature of participants of the trials
O'Connor, 1989 ¹⁰	4554 patients in 22 RCTs	All-cause mortality: OR 0.76, 95% CI 0.63 to 0.92 Cardiovascular mortality: OR 0.75, 95% CI 0.62 to 0.93 No reduction in non-fatal MI	Interventions and current health advice not adequately described in the included trials. Predominantly middle-aged white population
Jolliffe, 2003 ¹²	8440 post-MI patients in 32 RCTs	Exercise-only rehabilitation: All-cause mortality: OR 0.73, 95% CI 0.54 to 0.98 Cardiovascular mortality: OR 0.69, 95% CI 0.51 to 0.94 Comprehensive rehabilitation: All-cause mortality: OR 0.87, 95% CI 0.71 to 1.05 Cardiovascular mortality: OR 0.74, 95% CI 0.57 to 0.96	Also found improvements in cardiac risk factors
Taylor, 2005 ¹³	8940 patients: post-MI, PTCA and CABG in 48 RCTs 20% women	All-cause mortality: OR 0.80, 95% CI 0.68 to 0.93 Cardiovascular mortality: OR 0.74, 95% CI 0.61 to 0.96 No reduction in non-fatal MI or PCIs	Population of trials more representative of CR population. Subgroup analyses found no difference in effect sizes with trials before or after 1995, in MI vs other cardiac conditions, for exercise-only CR or for different doses of exercise
Clark, 2005 ¹⁴	21,295 patients with coronary disease in 63 RCTs	All-cause mortality: Exercise-only interventions: OR 0.72, 95% CI 0.54 to 0.95 Risk factor education only: OR 0.87, 95% CI 0.76 to 0.99 Exercise plus risk factor education: OR 0.88, 95% CI 0.74 to 1.04	English language studies only

OR, odds ratio; PCI, percutaneous coronary intervention.

Effectiveness in specific patient groups

Women and elderly patients have been under-represented in the trials of CR.¹² There is no evidence to suggest that either women or the elderly are likely to benefit less than younger men from CR; indeed, women often present with a lower level of physical fitness and so have more potential to benefit.^{19,20} Older patients may have differing goals from CR, placing more emphasis on regaining function than preventing future cardiac events.²¹ There is a paucity of information on the ethnic background of participants in the clinical trials, so evidence is lacking about effectiveness, but no mechanism has been put forward suggesting that rehabilitation should differ in effectiveness in ethnic minority groups.

Guidelines for cardiac rehabilitation provision

Guidelines from the USA, Australia and New Zealand recommend that CR should be provided for patients following MI, percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG),^{22,23} patients with angina²² and heart failure^{22,23} or other vascular or heart disease.²³ The Canadian Association for Cardiac Rehabilitation recommends that CR should be considered as standard care for almost all patients with documented cardiac disease.²⁴

UK policy

In England, the National Service Framework for CHD identifies patients who have had an MI,

PTCA or CABG as priorities for CR provision. When this is available to all patients with these conditions who wish to take up the service, then it is recommended that CR be offered to patients with angina and heart failure. In Wales, CR is advised for all patients who have had an acute coronary syndrome.²⁵ In Scotland, the Scottish Intercollegiate Guidelines Network (SIGN) recommends that CR is offered to patients post-MI and revascularisation and should be considered for patients with angina and heart failure.⁹

Provision of cardiac rehabilitation in the UK

A detailed survey of English CR services was published in 2006.²⁶ This found that many services were understaffed compared with the SIGN recommendations.⁹ Although all services offered CR to patients following an MI or CABG, 14% did not offer CR post-angioplasty and the majority of surveyed services (79%) offered less exercise than recommended in the SIGN guidelines. The level of funding provided to the services was below that considered necessary by the SIGN guidelines and a recent study in England²⁷ found services were inadequate for the minority of cardiac patients who do attend. Deficiencies of the services were considered to be due to inadequate funding and a low priority given to it by cardiology services and Trusts.

Models of cardiac rehabilitation

CR is predominantly provided in centres where patients can be monitored and supervised. In the UK, the majority of centres are on hospital sites.²⁶ The National Service Framework for Coronary Heart Disease guidance to increase uptake and broaden the range of patients offered CR places increasing demands on service provision and many programmes are developing community- and home-based services. Community-based services are often run by a community CR team and offer a similar service to the hospital service, but often to the lower risk patients. Home-based programmes were first described in the mid-1980s and range in level of intensity and supervision, including telemetrically monitored exercise at home on bicycle ergometers,^{28–31} home visits from physicians or nurses^{32,33} or a manual and telephone support.^{34,35}

Uptake and adherence

Overall uptake rates

Despite the evidence for its effectiveness, uptake rates to CR programmes are low. Surveys from the UK show levels of participation between 14 and 43%.^{7,36–39} Similarly low uptake rates are reported from Australia,⁴⁰ New Zealand,⁴¹ the USA^{42–44} and France.⁴⁵

Of those patients who do attend hospital CR, the drop-out rates from exercise programmes generally range from 20% in the first 3 months to 50% at 6 months to 1 year, but can be as high as 87% by 1 year.⁴⁶ Drop-out rates have been reported to be higher in high-intensity exercise programmes and poorly organised programmes. Smokers, patients who have had more than one MI^{46–48} and women are more likely to drop out.⁴⁹

Uptake and adherence in under-represented groups

The attendees of CR programmes have traditionally been white, middle-aged males following MI, whereas women and elderly patients were less likely to be invited or to participate once invited.^{5,50,51} In addition, patients with greater degrees of functional impairment are also less likely to participate.⁵² Patients with non-cardiac medical disorders are more likely to be excluded from CR,⁵³ in particular patients with musculoskeletal problems,^{39,54} respiratory disorders,⁵⁰ depression⁵⁵ and poor cognitive functioning.^{50,56–58} Patients living in areas of high socio-economic deprivation are also less likely to participate, but there is relatively little information about attendance by ethnic group. A study in the USA reported a higher drop-out rate of black women from a CR programme compared with white women, despite a greater prevalence of risk factors in the black women.⁵⁹ Non-English-speaking patients were reported to be less likely to attend CR in a Canadian survey.⁵⁰ An audit in the UK found that South-Asian patients were less likely to have attended CR, largely due to communication difficulties.⁶⁰ A systematic review of determinants of referral to cardiac rehabilitation in 30,333 participants in 10 observational studies from the USA, Australia and Canada found that speaking English was strongly associated with referral to CR [relative risk (RR) 9.56, 95% confidence interval (CI) 2.18 to 41.93].⁶¹ However, these studies had a very low overall rate of participants from an ethnic minority group.

In addition to reports of poor uptake and adherence to programmes, there are concerns that

although participants in centre-based programmes take sufficient physical activity on the days when they attend their programme, they may take insufficient amounts on other days.⁶² Home-based programmes could address this problem as participants are encouraged to build an exercise regime into their daily lives.

Reasons for poor uptake and adherence

Barriers to uptake of and adherence to a CR programme fall into three categories: patient factors, service factors and professional factors.⁶³ Patient factors include work or domestic commitments,^{20,39,64,65} a lack of interest in rehabilitation or a reluctance to change their lifestyle,⁶⁵⁻⁶⁷ a dislike of groups,⁶⁸ patient depression,⁵⁵ living in a rural setting^{50,69} and lack of support from the family.^{54,65}

Difficulties with accessibility of programmes and parking problems are commonly cited as a reason for poor adherence.^{53,70} In the USA, reimbursement issues affect uptake, with fee for service patients more likely to receive rehabilitation than patients in health maintenance organisations.⁷¹

Referral to CR is associated with professional belief in its effectiveness.^{50,58,72} Referral by a cardiologist has been shown to improve uptake.^{39,50,73,74}

Qualitative insights into the reasons for low uptake and adherence

Most of the studies exploring factors which are associated with attendance at CR are quantitative and provide limited insight into how these factors affect individual patients' behaviour and what developments in service provision would lead to improved access to and participation in CR programmes, particularly as many of the factors which predict lower attendance, such as increasing age, female sex, level of education and deprivation, are not amenable to change. Qualitative studies can give a greater understanding of how patients understand their illness and recovery and view participation in a rehabilitation programme, and several recent studies have begun to explore these issues.

Inadequate service provision was a major finding of a study that explored barriers to participation as perceived by both patients and healthcare professionals.⁷⁵ Service factors such as lack of services, long waiting lists, exclusion criteria and poor communication leading to delays and confusion prevented patients accessing services

when they most needed them. A lack of understanding and a perception of inappropriateness by patients contributed to limited participation in CR.

Two studies have explored patients' views following a cardiac event but before attending a CR programme. Patients interviewed in hospital following cardiac surgery associated CR with recovery from heart surgery and only a few understood it to be about long-term lifestyle change to maintain their health.⁷⁶ Transport difficulties and caring responsibilities were most commonly predicted by patients to be barriers to attendance. Similarly, an interview study of patients after discharge from hospital following an MI revealed deficits in some patients' knowledge about course contents and also misunderstandings about the role of exercise and its effects.⁷⁷ This resulted in some patients thinking that CR was not appropriate for them.

In an earlier study of patient preferences for CR in an area with no CR programme, the interventions requested most frequently were exercise sessions, group sessions, one-to-one counselling and relaxation.⁶⁸ The patients came from a region with urban and rural areas and the location of CR programmes was seen as the most important factor that would influence attendance. However, these patients also reported that the factor that most limited the amount of exercise they took, particularly walking, was bad weather, and this has implications for home-based programmes involving walking, which have been suggested for rural areas.

Several studies have compared the views of attendees, non-adherers and non-attendees at CR. A study which specifically explored the views of patients from ethnic minorities about attending CR identified several barriers to participation, in addition to factors such as language barriers and transport problems which have previously been associated with non-attendance at CR.⁷⁸ These included poor experience of healthcare during the acute event, religious insensitivity and attribution of the health problem to stress and worry so that an 'exercise programme' may seem irrelevant. However, the majority of respondents described making changes to their lifestyle, particularly dietary changes, with attendees making more changes than non-attendees.

An interview study of patients' decisions to attend a CR programme identified several themes which differentiated between three groups of patients:

those who attended, those who accepted an offer to attend CR but did not attend, and those who declined and did not attend.⁷⁹ Patients' perceptions of the causes and severity of their illness, their coping strategy and control over their recovery affected their decision to participate. The majority of attendees held a psychological model whereas all the non-attendees held a medical model and viewed their recovery as the responsibility of the medical profession and attached greater importance to their medication. A focus group study which explored the views of three groups (full, partial and non-attendance) also found that patients in the high-attendance group saw themselves as more active and capable in managing their CHD, whereas the low- and non-attendance group put greater emphasis on stress as a cause of CHD and saw themselves as relatively helpless in combating the progress of their disease.⁸⁰ This study also identified embarrassment at exercising in a group as an issue for patients but the high-attendance group appreciated the support and encouragement that they received from other attendees.

Recurring themes in qualitative studies are the lack of understanding by patients of both the content of CR programmes and the benefits of participation. These misconceptions play an important part in patients' decisions not to attend. Patients' attitudes and preferences for rehabilitation need to be explored if attendance and adherence are to be improved. Thus, for example, providing more accessible services in the community may not necessarily encourage attendance by patients who believe that CR is for younger or fitter patients.

Need for alternative models of cardiac rehabilitation to improve uptake and adherence

Effectiveness of home-based cardiac rehabilitation programmes

A systematic review comparing home-based CR with usual care reported a statistically significant reduction in systolic blood pressure (SBP) and a lower risk of being a smoker at follow-up in the home-based group.⁸¹ Non-significant improvements in exercise capacity, total cholesterol (TC) and anxiety and depression were also seen in the group receiving home-based CR, but total mortality was non-significantly higher in the home-based group. This review was hindered by the wide variety of the home-based CR

interventions, the poor reporting of the quality, the small size of many studies and the variety of outcome measures used. No differences were found for the varying types of CR (exercise only, comprehensive or predominantly psychological or educative), or for selected patient groups (post-MI or post-revascularisation).

Previous trials comparing home-based with centre-based cardiac rehabilitation

There have been several RCTs comparing home- with centre-based CR for patients post-MI and post-PTCA. These have shown no significant differences in outcomes between the programmes for exercise capacity, cholesterol, blood pressure, psychological status and smoking cessation, but the numbers included in the trials have been small.⁸¹ Two previous RCTs compared the Heart Manual with hospital-based cardiac rehabilitation.^{34,82} Neither study found significant differences between the patients allocated to the home- or hospital-based arms. Both studies were sited largely in southern England and took place in medium-sized towns with low proportions of ethnic minority residents.

What this study aims to add

The Birmingham Rehabilitation Uptake Maximisation (BRUM) study aimed to evaluate the Heart Manual on a wider, more representative patient population than previous studies. It was therefore sited in a multi-ethnic urban population with high levels of socio-economic deprivation and included patients following coronary artery revascularisation for the first time.

Patient preference

Patients express preferences for the location of a CR programme according to a range of personal factors. A study in the USA reported a preference for a home-based programme among older patients, whereas younger patients preferred a centre-based comprehensive programme.⁸³ A small Canadian study identified time-constrained, working cardiac patients as most likely to prefer home-based programmes, with no difference in preference on the basis of age or sex.⁸⁴ A study set in rural England reported that, when given the choice, 47% of patients opted for home-based cardiac rehabilitation, with older patients and the self-employed more likely to choose the home programme.⁸⁵ Patients choosing the home-based programme cited distance from hospital and parking problems as influencing their decision, whereas patients opting for the centre-based programme cited peer support and discipline as reasons for their choice. In a study in which

qualitative interviews were carried out with survivors of MI in Scotland, 38% did not want to attend a group for rehabilitation.⁶⁸ Some evidence supporting the hypothesis that providing home-based CR will increase uptake rates comes from Australia, where an additional 26% of cardiac outpatients chose to undertake CR after a home-based programme was introduced.⁸⁶ The lack of financial support for home-based programmes in the USA has hindered their development,⁸⁷ but no such barrier exists in the UK.

Economic and costing studies

A recent Health Technology Assessment (HTA) report⁶³ based a detailed costing on the staffing mix of 30 UK CR programmes with estimates of the overheads, building capital and equipment costs included, using costs for 2000–1. This suggested an average staffing cost of £354 and a weighted total average cost to the health service of £486 per patient successfully completing the rehabilitation programme. When the costs were spread over all patients referred to CR, the staff costs were £157 and total costs £220, and when spread over those people who commenced rehabilitation the staff and total costs were £269 and £371, respectively. The cost of the programmes increased as the number of different disciplines of staff who were involved in providing the programme increased.

Five previous studies reporting the costs of CR in the UK have been published.^{37,88–91} The costs vary hugely depending on the intensity of the programme, level of staffing, location of programme and equipment used, and all have been from the perspective of the NHS. A survey undertaken by the British Association of Cardiac Rehabilitation and British Heart Foundation reported costs to range from £50 to £712 per patient using costs for 2000.³⁷

A number of cost-effectiveness models have been produced for different healthcare systems. A cost-effectiveness and cost-utility analysis in the USA⁹² was based on one meta-analysis,¹¹ and the costs have been recalculated to reflect UK costs.⁹³ The UK results suggest a cost to the NHS per life-year gained at 3 years of £15,700 and a cost per quality-adjusted life-year (QALY) of £6900 (based on 1994–5 prices). A Canadian study used subjects from the 1992 Canadian Heart Health Study with known cardiovascular disease and assuming an adherence of 50% to CR estimated a cost of less than \$15,000 per year of life saved for men and a

higher figure of \$20,000–42,000 depending on the age of the woman (1996 US dollars).⁹⁴ An RCT based in Italy reported lower direct costs in the home-based programme, as a result of lower programme costs and reduced healthcare utilisation.⁹⁵

One systematic review of economic evaluations of CR which compared home-based with supervised CR has been published.⁹⁶ This identified four evaluations of home-based CR compared with supervised provision^{28,97,98} and one study has been published after the review.⁹⁹ Of the five evaluations, four were in the context of RCTs with follow-up from 6 months to 2 years. All were cost analyses, and Taylor's study was prospectively undertaken as part of an RCT.⁹⁹ All reported cost savings in patients participating in the home-based compared with the supervised centre-based programme, with savings to the NHS ranging from £30 per patient in a UK programme (2002–3 British pounds) to \$9575 in an Italian programme (2000 US dollars, health service perspective). Apart from the study reporting a UK hospital programme,⁹⁹ the centre-based programmes in this review consisted of sessions held three or four times each week for 8–23 weeks, which is of a greater intensity than usually provided in the UK and hence likely to be more costly than UK centre-based programmes.

Aims and objectives of the study

The BRUM study aimed to compare the outcomes of home- and centre-based CR in terms of cardiac risk factors and adherence to rehabilitation 6, 12 and 24 months after recruitment following MI, PTCA or CABG and to determine reasons for non-participation. We hypothesised that participants of the home-based programme might sustain improvements in capacity after the end of the programme better than those in the centre-based group as they would have the opportunity to build their physical activity regime into their lifestyle from the start of their CR programme.

The specific objectives were to determine:

1. Whether there are differences at 6, 12 and 24 months following centre- and home-based CR in
 - (a) objective cardiac risk factors (blood pressure, smoking, serum cholesterol, psychological status and exercise capacity) and

- (b) patient-reported uptake and adherence and
 - (c) whether these differ between patient groups (the elderly, women and patients from ethnic minority groups).
2. The relative costs of centre- and home-based CR from both societal (the patients') and NHS perspectives.
 3. Qualitative insights into the reasons for non-participation in the CR programmes.
 4. Whether there are differences in cardiac clinical events (MI/death from cardiac cause) at 2 years following centre- and home-based CR.

Chapter 2

Methods

The study population

Patients who had an MI, PTCA or CABG were recruited between 1 February 2002 and 31 January 2004.

Setting

The study took place in the West Midlands Health Region of England. Patients were initially recruited from two hospitals from one Trust in central Birmingham (Hospital 1) and the Black Country (Hospital 2). Both serve deprived, mixed-race, inner-city populations; Hospital 2 was in a Health Action Zone (an area with additional government money to address socio-economic deprivation). The catchment for the two hospitals has a high proportion of people from ethnic minority groups: approximately 25% mainly Asian and Afro-Caribbean at Hospital 1 and 16% at Hospital 2. Given the high incidence of CHD in people of South Asian origin, and the low uptake of CR in people living in deprived circumstances,³⁹ this made it an ideal population in which to study the uptake of CR. In addition, work conducted locally had identified that patients of South Asian ethnicity are less likely to take exercise and have a lower awareness of what constitutes a healthy diet than the white population.^{100,101}

As a result of a slower than predicted recruitment rate, two additional hospitals in the West Midlands joined the trial for the last 7 months of recruitment. These were part of a combined hospital Trust. Hospital 3 served a deprived, inner-city, multi-ethnic population, whereas Hospital 4 served a more affluent population.

Study design

The trial was a pragmatic, two-arm RCT of patients following MI or revascularisation, using individual patient randomisation.

Patients were identified by CR nurses following hospital admission for MI or PTCA. Patients following CABG were followed up and referred for rehabilitation at their hospital of origin, although

the referral process is often slow. All eligible patients were informed about the study prior to hospital discharge and asked if they would consent to randomisation. Punjabi-speaking patients who did not speak English were provided with a tape recording of the patient information leaflet in Punjabi to ensure that informed consent was explained in their native tongue and that this was the same for all participating patients. A Punjabi-speaking research nurse undertook the consent process to ensure that there was an opportunity for questions to be answered. Patients were not excluded from the study on the grounds of age.

Inclusion criteria

Adult patients following an MI or revascularisation (PTCA/CABG) with no upper age limit were eligible. At the start of the study, the definition of MI was under debate as a result of the definition from the Joint European Society of Cardiology/American College of Cardiology Committee:¹⁰²

“Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following:

1. ischaemic symptoms
2. development of pathological Q waves on the ECG
3. ECG changes indicative of ischaemia (ST segment elevation or depression)
4. coronary artery intervention (e.g. coronary angioplasty).”

Not all the cardiologists in the hospitals were using the new guidelines. Patients who fulfilled the criteria for MI were only eligible for CR if they were told they had had a heart attack. Patients defined as having had unstable angina were not eligible for rehabilitation. The inclusion criteria therefore had to include the patient having been informed about their diagnosis.

Any adult patient was eligible if they had had one of the following events within the previous 12 weeks:

- an acute MI **and** had been informed of their diagnosis
- a coronary angioplasty with or without stenting
- a CABG operation.

Exclusion criteria

Exclusion criteria were defined by a cardiologist:

1. inability to speak either English or Punjabi
2. case-note reported dementia
3. severe hearing impairment
4. sight defects of sufficient severity to prevent them from reading the Heart Manual
5. serious persisting complications which had not been stabilised at the time of proposed randomisation, including:
 - (a) unstable angina (angina at rest or minimal exertion, with ECG changes and requiring medical/non-medical intervention)
 - (b) clinically significant heart failure
 - (c) important cardiac arrhythmias
 - (d) any other condition which, in the consultant's opinion, would preclude safe home exercise
6. complications during the angioplasty/CABG procedure or significant lesions remaining.

Ethics committee approval

The study was approved by the four local research ethics committees serving the four hospitals.

Allocation to trial group

Patients who consented to randomisation were randomised on an individual basis with minimisation by (1) original diagnosis (MI/revascularisation), (2) age (<50/50–74/75+ years), (3) sex, (4) ethnicity (Caucasian/Asian/other) and (5) hospital of recruitment.

Allocation was undertaken by the Birmingham Cancer Clinical Trials Unit, a group that was independent from the trial team. A customised computer program was prepared by the Trials Unit. When a patient agreed to be randomised, following completion of the baseline questionnaire and clinical measurements, the research nurse telephoned the Clinical Trials Unit, provided the patient's demographic details and was given an allocation group.

Content of interventions

All the rehabilitation programmes included exercise, relaxation, education and lifestyle counselling, with referral for psychological treatments as indicated. All patients were seen by a CR nurse prior to hospital discharge and provided with information about their condition and counselling about risk factor modification.

The programmes are summarised in *Table 2* and detailed below.

Hospital-based cardiac rehabilitation

At Hospital 1, all patients were offered an individualised rehabilitation programme consisting of risk factor counselling, relaxation and twice-weekly supervised exercise sessions for 12 weeks. The exercise was mainly walking, fixed cycling and rowing. Participants built up to 25–30 minutes of continuous cycling over the programme working to 60–75% of maximal heart rate, depending on risk stratification. The relaxation session and information sessions occurred once during each rehabilitation session and participants could opt to attend. Patients completed the programme after attending 24 sessions.

Hospital 2 offered a more traditional 9-week course consisting of patient education and counselling and relaxation. The intention was for twice-weekly sessions of exercise, but due to a major fire at the hospital and the loss of the gym space for the CR team, exercise sessions only took place once each week during the period of the trial. Each session lasted 1.5 hours with the exercise consisting of circuit training with six stations. Patients did 1–2 minutes of each exercise with additional walking. In addition, the patients received further follow-up and support in cardiology outpatients.

The rehabilitation programme at Hospital 3 lasted for 8 weeks and consisted of eight sessions of education and exercise twice weekly over 4 weeks lasting 2.5 hours followed by a once per week hour-long exercise session for a further 4 weeks. Relaxation took place once per week. The exercise consisted of 45 minutes of circuit training. Patients aimed to exercise to 65–75% of maximal heart rate and were taught to monitor their pulse rate.

The CR programme at Hospital 4 consisted of 12 sessions held twice weekly over a 6-week period. The first eight sessions consisted of 30 minutes of education followed by a warm-up, 40 minutes of exercise on bicycles and treadmills and relaxation. This was followed by four further hour-long exercise sessions. Patients aimed to exercise to 65–75% of maximal heart rate and were taught to monitor their pulse rate.

The same cardiac rehabilitation team covered Hospitals 3 and 4, with some staff working in only one hospital and others covering rehabilitation sessions in both.

TABLE 2 Summary of cardiac rehabilitation programmes in the trial

CR programme	Duration/frequency	Physical activity component	Relaxation	Educational component
Hospital 1	Twice weekly 12 weeks	Walking, up to 25–30 minutes of fixed cycling, rowing Aiming for 60–75% max. HR	Voluntary part of session	Talk during each CR session: optional
Hospital 2	Weekly 9 weeks	Circuit training with 6 stations: 1–2 minutes per station and walking	Included in each session	Weekly as part of CR session
Hospital 3	12 sessions 8 weeks	45 minutes of circuit training Aiming for 65–75% max. HR Taught to monitor own pulse rate	Weekly, as part of session	8 sessions included education
Hospital 4	Twice weekly 6 weeks	1 hour with warm-up, 40 minutes of exercise on fixed bikes, and treadmills Aiming for 65–75% max. HR Taught to monitor own pulse rate	Part of each session	30 minutes education per session
Home-based programme: Heart Manual	Patient: daily Manual 6-week programme Nurse contacts in hospital, at home at 10 days, 3, 6 and 12 weeks	Daily exercise encouraged from hospital discharge. Home exercises working up to daily walking, then on to other enjoyable physical activity	Relaxation tapes provided and regular use encouraged	6 weekly chapters covering risk factors, lifestyle changes, medications
HR, heart rate.				

Home-based cardiac rehabilitation

This consisted of a manual, home visits and telephone contact.

Patients who had had an MI were discharged home with *The Heart Manual* (second edition).¹⁰³ Those who had had a revascularisation had an adapted version of the Heart Manual designed for this patient group in conjunction with the Heart Manual Team. The Heart Manual is a facilitated home-based programme for the first 6 weeks following MI, based on the Health Belief Model and using cognitive behavioural techniques. It includes education, a home-based exercise programme and a tape-based relaxation and stress management programme. It also has accompanying tapes in ethnic minority languages for patients who are unable to read English.

The Heart Manual was introduced to patients on an individual basis, either in hospital or on a home visit. The facilitators adhered to the format with which they had been familiarised at the Heart Manual training course. At this time the facilitator provided information about how they could be contacted and arranged a home visit for 7–10 days ahead. At the first visit the facilitator discussed the progress with the patient and agreed action or exercise goals with the patient. Patients were then telephoned at about 3 weeks post-recruitment and a further visit took place 6 weeks post-recruitment. A final visit took place at 12 weeks, when patients were encouraged to maintain their lifestyle changes and to continue with their exercise programme. Additional visits were made as deemed necessary by the rehabilitation nurse.

Patients with no telephone had home visits instead of telephone contacts.

Patients who had an insufficient command of English were followed up by a rehabilitation nurse who spoke Punjabi. An audiotape in Punjabi accompanied the Manual in patients with a limited command of English (as many non-English speakers of this age group are also illiterate¹⁰⁴). This tape was an abridged version of the Heart Manual. An English Manual was also given to the patient, and a relative who could read English was encouraged to work through the Manual with the patient.

Training of nurses

All the nurses who provided the home-based CR programme attended a 2-day training course run by the Heart Manual Team.

Outcome measures

Recruitment took place over 2 years.

Primary outcome measures

CR is a broad intervention with holistic aims. Due to its focus on increasing physical exercise, smoking cessation, improvement of diet and a reduction in psychological morbidity, it is not appropriate to give one outcome measure primacy. If a CR programme has a high patient uptake and adherence and is effective, it will lead to reductions in risk factors, which in turn should translate to a reduction in cardiac events.^{48,105–114} At 1 year mortality rates are low (6% in Jolly and colleagues¹¹⁵) and it is unlikely that one would see a reduction in cardiac events. It is also possible that revascularisation rates could be associated with participation in a particular rehabilitation programme. The primary outcome measures thus consisted of a number of cardiac risk factors as follows.

Serum cholesterol

Serum cholesterol was measured by the clinical chemistry department at the recruiting hospital.

Blood pressure

Blood pressure (assessed according to BHS Guidelines) measured three times on each occasion and the mean of the last two readings taken.

Exercise capacity

Exercise capacity as assessed by the incremental shuttle walking test (ISWT). There is a good correlation between ISWT and $V_{O_2 \max}$ in patients with heart failure,^{116,117} and of its reproducibility to show differences in exercise capacity in patients with cardiac pacemakers¹¹⁸ and chronic heart failure.¹¹⁷ At the 6-month clinical assessment patients did a practice ISWT, then rested for at least 30 minutes before completing the actual ISWT. Reasons for termination of the test were recorded. At the 1- and 2-year assessments the practice ISWT was omitted.

Psychological morbidity

The Hospital Anxiety and Depression Scale (HADS)¹¹⁹ was selected because it had already been used in a number of UK trials of CR. The scale is a brief measure of both anxiety and depression without contamination from physical symptoms. Higher scores indicate greater levels of anxiety and depression. The English version has been found to be reliable and valid.¹²⁰ Asian patients completed a translated Punjabi version, which was validated prior to the start of the trial.

Cotinine-validated smoking cessation

Smoking was measured by self-report with a urine sample taken from patients who reported a history of having 'ever smoked'. This was assessed for cotinine using a colorimetric assay 'SmokeScreen Test'.¹²¹ Results were categorised into non-smokers and evidence that the patient was still smoking.

Secondary outcome measures

There were several secondary study outcome measures collected at 6, 12 and 24 months after recruitment: (1) measurement of uptake and adherence; (2) self-reported behaviour, symptoms and secondary preventive medication; (3) quality of life; and (4) death and other cardiac events.

Uptake and programme adherence

Patient uptake and adherence to the programmes were of primary interest because of the poor uptake and adherence rates reported in the literature, particularly in women, the elderly and people from minority ethnic groups. However, there are potential difficulties in obtaining unbiased measures of these, as attendance at a hospital programme cannot be equivalently compared with acceptance of a home visit. Patient-completed activity questionnaires (modified Godin) were used for both groups. Although providing a similar measure in both groups, there were different frequencies of contact with health professionals and thus 'cues' to complete the questionnaires, and so these data are not incontrovertibly comparable, but are likely to be better than other measures of uptake in these circumstances. Uptake was defined as self-reported activity levels during the rehabilitation programme. The frequency of activity was from none to five times or more in the previous 7 days at three levels of intensity (mild, moderate and vigorous). The frequency score (0, 1, 2, 3) was multiplied by two for moderate activity and by three for vigorous activity to derive a score with a maximum possible of 18. Duration of reported exercise at 6, 9 and 12 weeks was used to compare adherence, again with the hours multiplied by two for moderate and three for vigorous activity.

Self-reported behaviour

Self-reported diet was measured using single items from a food frequency questionnaire (Appendix 1). Many dietary questionnaires require administration by a researcher, and most were considered too lengthy to be included. Only those questions relating to foods considered either particularly beneficial or advised to be cut down

were included. Physical activity levels were measured using the exercise component of the Health Behaviours Profile¹²² (a modified Godin questionnaire¹²³). Again, many questionnaires of physical activity are fairly long and over-burdensome for use as a secondary outcome measure. The modified Godin was used in the Health and Lifestyle survey and had been used by the lead author in a previous study and had had a good completion rate. The physical activity score was a maximum of 18, with up to three points for mild activities, six points for moderate physical activities and nine points for vigorous activities. The duration of physical activity was weighted, with time spent in moderately intense activities multiplied by a factor of two and in vigorous activities by three.

Healthcare utilisation

The main data were self-reported utilisation of primary and secondary care services, including hospital admission and attendance at a Phase IV CR programme. Use of secondary preventive medication and patient satisfaction with the programmes were also recorded. The hospital admissions were validated against the computerised hospital records, for the majority of the self-reported admissions, but were found to be very similar to the self-report, which was used for the economic analysis.

Cardiac symptoms

The frequency and severity of angina and shortness of breath were collected.

Body mass index (BMI)

Height was measured at baseline using a Seca Leicester portable height measure. Weight was measured using Seca 880 scales. BMI was calculated as weight/(height)².

Quality of life

Quality of life [EuroQol quality of life (EQ-5D)¹²⁴] data were collected for the economic analysis. The Short Form with 12 Items (SF-12)¹²⁵ and the Global Mood Score (GMS)¹²⁶ were also included. The GMS was chosen because it has been shown to be sensitive to change and is able to capture the positive changes resulting from CR (as opposed to the absence of negative changes).^{127,128} The SF-12 and GMS were not used at baseline to reduce the burden of questionnaires in the patients. In addition, piloting of the SF-12 showed that patients who were post-infarct were unable to describe their health over the previous 7 days as they had had a huge change in health status during this time.

Death and cardiac events

Death and cardiac events (MI, PTCA, CABG) were recorded. The cardiac events were self-reported and validated, where possible, from the hospital records.

Data collection**Baseline data**

An eligibility and randomisation form was completed for all patients presenting to the hospitals following an MI, PTCA or CABG. This form recorded brief demographic details and reasons for ineligibility or declining to participate in the trial.

Eligible patients who gave informed consent to the trial signed a consent form and completed a baseline questionnaire, including demographic details, self-reported health behaviours, psychological status and quality of life. The research nurse measured baseline clinical indices, including weight, height and blood pressure. The serum cholesterol level from the patient's index admission was used.

Outcome data

The first follow-up assessment took place at 6 months after recruitment and consisted of a postal questionnaire and clinical assessment. Two further assessments at 12 and 24 months were undertaken. Assessments were blinded, with follow-up undertaken by a research nurse who had neither recruited the patient nor provided home CR support. Participants received the follow-up questionnaire approximately 2 weeks before their follow-up appointment was due. An accompanying letter informed them that they would be contacted by a research nurse who would organise a follow-up appointment. They were asked to complete the questionnaire at home before their appointment and to bring it, with their medications, to their follow-up appointment. They were told that assistance would be provided if they needed help completing the questionnaire. Participants were telephoned to organise an appointment time, and then telephoned on a second occasion, if possible, to remind them to attend. Participants who failed to attend their follow-up appointment were offered appointments on two further occasions and then a home visit to maximise follow-up rates.

At the 6-month clinical assessment, patients did a practice ISWT, then rested for at least 30 minutes before completing the actual ISWT. Reasons for termination of the test were recorded. In addition, a blood sample was taken for serum cholesterol and high-density lipoprotein (HDL) measurement;

a urine sample for urinary cotinine for all patients who had a history of smoking; blood pressure and weight were measured.

If patients had contraindications to doing the ISWT, then this was omitted. Patients who were too unwell or were unwilling to attend for the follow-up assessment were offered a home visit. All the clinical measurements, except the ISWT, were possible in the home environment.

Process data

Questionnaires were sent at 6, 9 and 12 weeks after recruitment to all participants, asking about the intensity and duration of physical activity they had undertaken in the previous 7 days. As the participants received the next questionnaire only 3 weeks after the first, previous one, each questionnaire was sent only once.

In addition, the records of the CR programmes were used to record the number of attendances at the hospital rehabilitation programmes of trial participants. These data were of variable quality, with differences between the paper and computer records noted on a number of occasions.

The research nurses who provided the home programme recorded the number of visits and telephone calls made to each patient.

Sample size

Our initial estimate assumed 30% attrition at 1 year due to death and loss to follow-up (15% in Jolly and colleagues¹¹⁵). This required a sample size of 650 patients (450 evaluable at 1 year) which would have 90% power, at the 5% significance level, to detect the differences tabulated below [population standard deviations (SDs) estimated from Jolly and colleagues¹¹⁵]. Differences larger than these would have clinically significant effects (*Table 3*).

As a result of a slower than predicted recruitment rate, with a high follow-up rate at 6 months, we reduced the required sample size to 525 participants. With 90% follow-up at 1 year, 80–90% power would be achieved for all the primary outcome measures.

Analysis

The data were entered into an ACCESS 2000 database (Microsoft Windows). The Statistical

TABLE 3 Sample size calculation

End-point	Study has 90% power to detect difference	Assumptions	Precision of estimate	
			95%	99%
Mean serum cholesterol (mmol/l)	0.4	SD = 1.3	±0.24	±0.32
Systolic blood pressure (mmHg)	6	SD = 21	±3.9	±5.1
Shuttle-walk test/10-m	6	SD = 20 ^a or	±3.7	±4.9
Shuttles		SD = 40	±7.4	±9.7
HADS anxiety score	1.5	SD = 4.5	±0.83	±1.1
HADS depression score	1.5	SD = 4.0	±0.74	±0.97
Smoking cessation	20% ¹¹⁵	45% smokers at baseline (effective sample size ~200) 50% give up in hospital-based group	9%, 33%	5%, 37%

^a SD 19 reported in Keell and colleagues,¹¹⁶ but this study was in 50 male patients with established left ventricular dysfunction (mean 38, range 4–102). No other selection criteria stated, but may have been relatively highly selected and thus a substantial underestimate of the SD for our population. Further estimates are given assuming an SD of our population of 40.

Package for Social Sciences (SPSS) version 12 and Stata version 7 were used for analysis.

All data were analysed by intention-to-treat (ITT).

For cardiac risk factors measured on a continuous scale (serum cholesterol, SBP, exercise capacity, HADS anxiety and depression), differences in means between the two groups were investigated. Differences in smoking cessation were assessed amongst those who were smokers at baseline using the Cochran–Mantel–Haenszel χ^2 test for a difference in proportions; CIs were calculated using the equation due to Cochran.

Secondary analyses were conducted for each primary outcome measure adjusting for diagnosis (MI/revascularisation), age, sex and ethnicity, and also centre and baseline measurement (logistic regression was used to provide adjusted analyses for smoking cessation). Baseline measurements for exercise capacity were not available; for the other measures, analysis of covariance was used to take into account the baseline measurements for each patient. When baseline information is available, this provides a more precise estimate of the treatment effect than either raw outcomes or change scores.¹²⁹ Interaction terms between these factors and rehabilitation setting were included to investigate possible differences in treatment effect between subgroups of patients. Although the power to detect modest interactions is low, we were primarily interested in investigating the possibility

of large interactions which are qualitative rather than quantitative in nature, that is, the possibility that the **direction** of treatment effects may vary between groups of patients. It is reasonable to hypothesise that hospital-based rehabilitation may be more effective for those groups with high rates of uptake and adherence to hospital-based programmes whereas others may gain more from home-based care.

Before analysing measures of uptake and adherence derived from modified Godin questionnaires at 6, 9 and 12 weeks, we checked for bias in reporting between the groups. The data were compared (1) with the 6-month reported exercise, (2) with cardiac risk factors and (3) internally between different patient groups. Baseline characteristics were explored within the two treatment groups separately in order to identify predictors of uptake and adherence, based on both modified Godin questionnaires and attendance/home visit records.

Analyses of secondary outcomes were descriptive in nature.

Throughout the analysis, emphasis was placed on estimation rather than hypothesis testing. Where hypothesis tests were carried out, these were at the 5% level for primary outcome variables and at the 1% level for interaction terms. Although a strict Bonferroni adjustment for multiple testing would suggest the use of somewhat more conservative

significance levels (1% for primary outcomes), this adjustment is too conservative when outcomes are positively correlated, as they would be in this trial. Although alternative methods of adjustment are available, the performance of these methods depends heavily on the underlying data structure.¹³⁰ Multivariate methods, which model all outcomes simultaneously and provide a single 'global' test of significance, are available. However, univariate methods involve fewer distributional assumptions and are more straightforward to interpret. Furthermore, in this trial we were investigating what has been termed 'multiple univariate hypotheses' rather than a true (single) multivariate hypothesis; the univariate methods outlined above are therefore more appropriate.¹³¹

Given the multiple assessment points in this trial, analysis of variance (ANOVA)-based repeated measure analysis was used to assess between-group differences across all assessment points. Where a significant difference between groups across all time points was detected, paired *t*-tests were undertaken between successive time points.

The ISWT had the highest proportion of missing data at follow-up as some patients were too unwell or high risk to undertake the test. For other primary outcome measures, the proportion missing at 1 year ranged from 10 to 15%. A sensitivity analysis was undertaken on the 12-month data to assess the potential impact of the missing values for the ISWT, SBP, diastolic blood pressure (DBP), TC and the HADS scores. Absent values were assumed to be 'missing not at random'. Regression-based models at 12 months were developed to assess the relationship between covariates and outcome measure in completers.¹³² Missing cases were substituted with a predicted outcome value.

Qualitative studies

Aims of the qualitative studies

These studies explored patients' reasons for non-participation in/non-adherence to a home- or hospital-based CR programme through semistructured interviews. In order to compare the views of patients who had not adhered to their CR programme with those who had, a series of focus groups were undertaken with hospital- and home-based programme adherers. Interviews were also sought with minority language speakers to find out their experience of the CR programmes, in particular the Punjabi tapes of the Heart Manual.

Recruitment of participants who did not adhere to a cardiac rehabilitation programme

Patients for interview were recruited from those taking part in the trial. Sampling was purposive and patients were invited for interview until at least 10 had been interviewed from each of the categories: female, elderly (aged 70 years and over), minority ethnic group and middle-aged men. The nurses involved in both the hospital- and home-based rehabilitation programmes provided information about patients who, in their view, had declined or not adhered to a programme. For patients on the hospital-based programmes, data on the number of sessions attended by each patient were also used to identify patients for interview, although these data were generally only available some time after completion of the programme. Where attendance data were not yet available, study data from the physical activity questionnaire completed by patients about their level of physical activity 9 weeks after recruitment into the trial were used to assess which patients had very low levels of physical activity and were therefore less likely to have adhered to the programme. For the home-based programme patients, recruitment for interview was based initially on the perception by the study nurses of whether a patient had adhered to the programme. In addition, the information from the 9-week physical activity questionnaire was used to assess whether patients should be invited for interview.

Attempts were made to contact 74 patients by telephone. Six telephone numbers were incorrect and it was not possible to find an alternative number through directory enquiries. One patient had died. Most patients were very willing to assist in the qualitative study and 50 agreed to be interviewed, but one of these was subsequently found to have attended all the sessions on the hospital-based programme. Ten patients could not be contacted and seven refused. Patients were asked if they were willing to be interviewed about their views and experience of their CR programme. Patients who agreed to an interview were sent a letter confirming the details and an information sheet explaining the purpose and conduct of the interview.

Interviews

All the interviews were conducted by one interviewer (MJ). Interviews were conducted in the patients' homes and patients were asked to sign a consent form before starting the interview. Interviews took place between 3 and 20 months

(mean 10 months) after randomisation into the trial. The interviews were tape recorded and transcribed. In one interview the recording failed and a summary of the interview was prepared (P25). Interviews usually lasted about 40–45 minutes but varied between 25 and 55 minutes; the word count of the transcripts ranged from about 2500 to 10,500 words.

The patient's partner was present in 14 interviews and the patient's daughter in two interviews and they also contributed to the interviews. Contributions ranged from limited interventions, for example to remind the patient of dates or a doctor's name, to interrupting and answering questions on the patient's behalf. One patient's daughter (P15), who arrived during the interview to interpret for her father who spoke limited English, also described how her father's condition affected the rest of the family.

Interview topics

The interview schedule was developed to include issues emerging from previous studies in the literature and from a previous study of CR patients.⁷⁸ The semistructured interviews covered various topics related to the patients' cardiac event, including:

- biographical information
- experiences before the cardiac event
- the event
- beliefs about heart disease
- lifestyle changes
- satisfaction with health service provision
- expectations and experience of their rehabilitation programme.

Recruitment to the focus groups of patients who adhered to cardiac rehabilitation

Three focus groups were organised for patients from the four hospital-based programmes and two for home-based programme patients. As the CR programmes at Hospitals 3 and 4 were run by the same team and were very similar, patients from these two hospitals were invited to attend the same focus group. Similarly, home-based programme patients from Hospitals 1 and 2 were invited together as they were supported by the same nurses, and patients from Hospitals 3 and 4 were invited to the same group.

The list of all patients taking part in the BRUM study was used to select patients to invite to the focus groups. Patients who were known not to have adhered to their programme were excluded

using the CR report and data on the number of sessions for each hospital programme which patients had attended. The selection of patients for the focus groups was purposive in order to include both men and women and patients from all age groups.

Patients were approached by telephone and asked if they had completed their CR programme. Patients who confirmed this were asked if they would be willing to attend and sent written confirmation if they agreed. Up to eight patients were invited to each focus group. Patients were offered reimbursement of their travel expenses. Of the 33 patients who agreed to attend, 26 attended on the day.

Recruitment to study of Punjabi speakers

Interviews were conducted with 10 minority language speakers in Punjabi. They were approached by telephone by a bilingual researcher and interviewed in their home. Topic prompts were the same as those used in the interviews of non-adhering patients.

Analysis of qualitative studies

Each transcript was checked for accuracy against the tape. The transcripts were analysed using the technique of charting.¹³³ This involved transcripts being read independently by three authors (MJ, SG, KJ) and the main themes and subcategories being identified and agreed. The transcripts were then re-read and the text marked where each theme was mentioned. Brief summaries of what each patient had said under each theme were grouped together in a list for analysis. Additional themes were added as further transcripts were analysed if the theme had not been identified in previous transcripts. Not all the patients mentioned each theme.

Economic study

Relevant resource usage was defined in relation to both NHS and societal perspectives. Resource use data were collected over the trial duration on each patient's use of the rehabilitation services (number of hospital sessions attended, number of home visits, duration of home visits) in addition to general practice and hospital services (both cardiovascular and all conditions). Drug use data for secondary prevention were collected at the start and at 12 months, as was employment status. Travel costs and travel time were based on distances from patients' addresses to the relevant centre.

Resources were valued using locally derived unit costs, mainly duration of sessions/visits and staff costs. Staff costs per hour, distinguishing whether patient contact or not, were based on Netten and Curtis,¹³⁴ which includes overheads. Travel costs were based on NHS costs for nurses and Automobile Association rates for patients. A shadow price for patient travel time was based on the minimum wage of £5 per hour.

The cost per patient in the home arm comprised the cost of the home visit, the cost of the nurse's travel and travel time and the cost of the Heart Manual (including training). The cost in the hospital arm within the NHS perspective comprised the cost of rehabilitation sessions attended. Patient travel-related costs (cost of travel plus cost of time spent travelling) were added to this to obtain a societal perspective.

Mean cost per patient in each arm of the trial was based on bootstrapping and tested for difference using both *t*-tests where appropriate and permutation tests (two-tailed for null hypothesis, one-tailed for difference). Arithmetic means were also used for comparison and as a check.

Changes to the project protocol

The protocol originally stated that we would provide materials in Punjabi and one other minority language. We restricted the study to English and Punjabi for a number of reasons:

- The large amount of work required to translate and validate the HADS into Punjabi and to produce the study and home-based materials in Punjabi.

- The nurse who was to do the home visits to the non-English speakers only spoke Punjabi.
- Punjabi was the predominant minority language spoken locally.

After piloting the baseline questionnaire, questions about the patient's home were dropped to reduce the length of the questionnaire, and the SF-12 was dropped as it was difficult to complete because it asks about health over the previous 4 weeks, which is difficult to describe given the huge change as a result of their heart attack.

Due to slower than predicted recruitment, two new recruitment centres joined the study and the recruitment period was extended. In addition, the target number of patients was reduced from 650 to 525 because the follow-up rates that we were achieving were much better than we had predicted (90% versus 70%). This did not change the power of the study.

The qualitative research was extended to include interviews (undertaken as focus groups) with patients who adhered to the rehabilitation programmes, to provide a comparison to the non-adhering patients who were interviewed. In addition, a small number of participants who spoke little or no English were interviewed for their experience of the rehabilitation programme.

Participants were asked about the costs that they incurred from their attendance at the rehabilitation programme. Also, the qualitative interviews sought to determine whether the costs of participating in CR contributed to non-adherence.

Chapter 3

Quantitative results

Recruitment and baseline details

Over the study recruitment period, 525 people were recruited into the trial, 263 to the home-based intervention and 262 to the centre-based CR programmes. Of the 1997 people who presented to the recruiting hospitals during the recruitment periods, 790 (39.5%) were excluded as ineligible for the study. The reasons for ineligibility are recorded in *Figure 1*, but fall into two main categories of being at too high a cardiac risk for home exercise, or having co-morbidities preventing participation in cardiac rehabilitation. In addition 29% of the presenting patients from ethnic minority groups were considered ineligible due to an inability for us to support their language requirements. Of the 1207 eligible patients 43.5% agreed to participate (26% of the total).

Recruitment by patient characteristics

Of the patients who were considered eligible for home-based CR, and hence the trial, women and the elderly were less likely to agree to randomisation (*Table 4*). There was no difference between patients with different diagnoses or different ethnic groups as to agreement to participate. Recruited patients had a similar Index of Multiple Deprivation (IMD) score to those who were not recruited [mean IMD (SD) 33.48 (16.3) versus 35.19 (17.7) for non-recruits]. Eligible patients who did not agree to be randomised were offered a number of possible reasons for declining. Almost half (49%) did not wish to take part in a research study, 15% did not wish to take part in CR, 12% wished to join the hospital-based programme and 23% gave no reason.

As the women were generally older than the male patients, a logistical regression analysis was undertaken with age, gender, ethnic group, presenting diagnosis and hospital of recruitment in the model. Only age was a significant factor predicting recruitment, with older patients (age 65+ years) less likely to be recruited (adjusted RR of recruitment 0.63, 95% CI 0.5 to 0.8).

Baseline characteristics of participants

The baseline characteristics of the participants in the two rehabilitation groups are shown in *Table 5*. Demographic characteristics, diagnosis, past

medical history and cardiac risk factors were well matched between the two arms at baseline. Approximately half of the participants had had an MI and half a revascularisation procedure. The sample was ethnically diverse, with 20.4% from an ethnic minority group, 23.4% were female, and the mean (SD) age was 61.0 (10.8) years.

Uptake and adherence data

The measurement of adherence had to be the same for both arms of the trial. We used a modified version of the Godin questionnaire, with questions about frequency and duration of physical activity. A questionnaire on at least one occasion at 6, 9 or 12 weeks was received from 452 (86.1%) of the participants. Response rates were similar in both the home-based (87.5%) and centre-based (84.7%) arms of the trial. Further details are given in *Table 6*.

Non-respondents were younger, more likely to be from an ethnic minority group, to be in paid employment and to have higher cardiac risk factors at baseline than respondents (*Table 7*).

The level of physical activity reported at 6, 9 or 12 weeks was divided into three categories: low (less than three periods of physical activity), moderate (three or four sessions of physical activity) and high (five or more periods of physical activity) in the previous 7 days. An additional category of non-responder was included. The physical activity scores at 6 months were calculated for the four categories. Non-responders to the adherence questionnaires had physical activity scores at 6 months similar to those reporting moderate physical activity in their adherence questionnaires, hence it seems that non-responders to the adherence questionnaires did not differ markedly in self-reported physical activity at 6 months (*Table 8*).

The National Service Framework for Coronary Heart Disease in England set a target that patients attending a CR programme should undertake three sessions of exercise each week, two of them supervised. *Table 9* shows the proportion of participants randomised to the home-based and

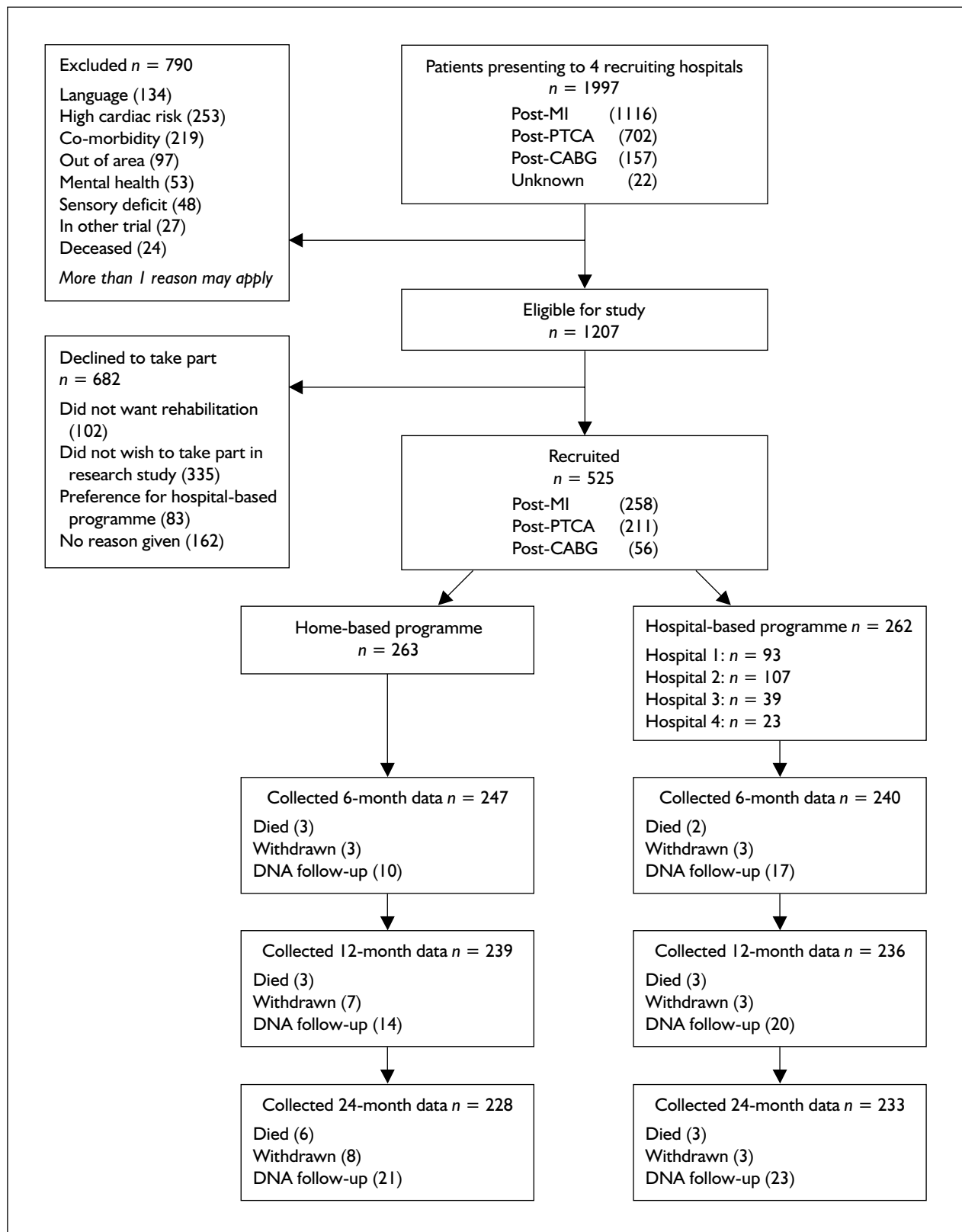


FIGURE 1 CONSORT (Consolidated Standards of Reporting Trials) diagram of recruitment to BRUM study

TABLE 4 Recruitment of eligible patients

	Eligible: n	Recruited		p-Value
		n	%	
Males	881	402	45.6	0.025
Females	321	123	38.3	
Age <65 years	659	322	48.9	<0.001
Age 65+ years	548	203	37.0	
MI	592	256	43.3	0.7
PTCA	467	211	45.2	
CABG	136	56	41.2	
White	927	418	45.1	0.7
South Asian	198	88	44.4	
Other ethnic group	44	19	43.2	

supervised arms who reported at least three episodes of physical activity in the previous week. This is significantly higher in the home-based arm at 6 weeks (95% versus 85%), but is no different at 9 and 12 weeks. This is explained by the fact that the Heart Manual commences the physical activity programme on discharge from hospital, but the hospital rehabilitation programmes start later, often 6–8 weeks after their cardiac event.

Tables 10 and 11 show the physical activity score and hours of physical activity by rehabilitation arm (both weighted for intensity). Patients randomised to the home-based arm reported significantly more hours of physical activity at each time point and a higher physical activity score at 9 weeks. Subgroup analysis identified higher physical activity scores and greater hours of physical activity reported by ethnic minority participants in the home-based arm and older participants in the home-based arm.

Attendance at the hospital rehabilitation sessions is reported in Table 12 and ranged from 42 to 72%. Overall, 28% of patients allocated to the hospital arm did not commence the hospital-based programme. The hospital-based programme with the highest proportion of sessions attended was the least intensive of the programmes and Hospital 4 with the next highest attendance rate served a more affluent population than the other hospitals. There were no differences in attendance rate by sex or ethnicity, but younger patients (age <50 years) attended a lower proportion of sessions.

Crossovers

During the first 6 weeks of the home-based CR programme, 11 patients crossed over from the

home- to the hospital-based programme. In eight cases this was due to the development of additional cardiac or medical complications, requiring closer monitoring, and in three cases a lack of motivation to exercise at home was the predominant factor. These participants were analysed on an ITT basis as part of the home-based group.

Six-month study outcomes

Completeness of data

Follow-up data were obtained on 485 (93%) of live participants at the 6-month follow-up. A high level of data completeness was obtained except for the ISWT, which was completed in 349 (80%) of patients followed up. Table 13 details the reasons for loss to follow-up and non-completion of the ISWT, which were mainly cardiac contraindications or other co-morbidities.

Primary outcomes

ITT analysis of the primary outcomes revealed no difference at the 6 month follow-up for SBP, DBP, TC, HDL-cholesterol, the HADS scores, distance walked on the ISWT or smoking cessation. When the analysis was adjusted for the randomising variables (age, sex, diagnosis, ethnicity and centre) and baseline value, there continued to be no significant differences (Table 14). The difference between the home- and centre-based arms in adjusted mean SBP is only 0.18 mmHg, but the CIs are consistent with the SBP in the home-based arm being 2.8 mmHg lower or 3.2 mmHg higher than that in the centre-based arm. The CIs around the TC, HDL-cholesterol and the HADS scores make it unlikely that we missed a clinically significant difference between the groups.

Secondary outcomes

Self-reported chest pain on movement and shortness of breath at rest and on movement were similar in both the home- and centre-based groups, although participants in the home-based arm reported slightly more chest pain at rest (Table 15).

There was no difference in self-reported diet at 6 months except for the slightly higher reporting of fruit and vegetable consumption in the centre-based group (Table 16).

Self-reported physical activity (modified Godin score) was similar in the two groups, as were the hours of physical activity reported (Table 17). Whereas the physical activity score increased from baseline to the 6-month follow-up, the hours of activity actually fell, despite the weighting for intensity.

TABLE 5 Baseline characteristics by study group

	Home-based	Centre-based
Sex: male, <i>n</i> (%)	203 (77.2)	199 (76.0)
Age: mean (SD) (years)	60.3 (10.5)	61.8 (11.0)
Ethnicity: <i>n</i> (%)		
White	211 (80.2)	207 (79.3)
Asian	43 (16.3)	46 (17.6)
Other	9 (3.4)	8 (3.0)
Living alone: <i>n</i> (%)	37 (14.1)	39 (14.9)
Access to a car: <i>n</i> (%)	206 (78.3)	205 (78.2)
Years in full-time education: mean (SD)	10.4 (3.5)	10.5 (3.3)
Currently employed: <i>n</i> (%)	109 (41.5)	111 (42.4)
Diagnosis: <i>n</i> (%)		
MI	129 (49.0)	129 (49.2)
PTCA	101 (38.4)	110 (42.0)
CABG	33 (12.5)	23 (8.8)
Past medical history: <i>n</i> (%)		
Hypertension	132 (51.2)	114 (45.6)
MI	43 (16.5)	54 (20.7)
CABG	16 (6.1)	10 (3.4)
PTCA (angioplasty)	24 (9.2)	24 (9.3)
Attendance at CR	25 (9.6)	37 (14.2)
Diabetes	35 (13.4)	36 (14.1)
Smoking history: <i>n</i> (%)		
Current smoker at heart attack	94 (35.7)	85 (32.4)
Ex-smoker	101 (38.4)	106 (40.5)
Lifetime non-smoker	68 (25.9)	71 (27.1)
Healthy food intake: mean (SD)		
Fruit and vegetables	3.42 (1.20)	3.52 (1.23)
Fish	1.37 (0.93)	1.52 (0.89)
Pasta	2.72 (1.00)	2.80 (1.00)
White meat	1.83 (0.79)	1.81 (0.84)
Unhealthy food intake: mean (SD)		
Fried food	1.50 (1.06)	1.31 (1.04)
Beef	1.80 (0.94)	1.78 (0.96)
Snacks	2.19 (1.42)	2.16 (1.32)
Physical activity: Godin score: mean (SD)	6.24 (3.75)	6.08 (3.80)
HADS anxiety score: mean (SD)	7.89 (4.52)	7.20 (4.23)
HADS anxiety score > 10: <i>n</i> (%)	65 (25.7)	60 (23.4)
HADS depression score: mean (SD)	4.92 (3.40)	4.76 (3.27)
HADS depression score > 10: <i>n</i> (%)	18 (6.9)	13 (5.1)
EQ-5D thermometer: mean (SD)	70.10 (19.64)	68.73 (17.78)
Clinical indices		
SBP: mean (SD) <i>n</i>	124.00 (17.27) 260	123.57 (18.32) 259
DBP: mean (SD) <i>n</i>	72.45 (11.09) 260	72.07 (10.55) 259
TC: mean (SD) <i>n</i>	4.75 (1.25) 259	4.75 (1.35) 249
HDL-cholesterol: mean (SD) <i>n</i>	1.21 (0.55) 217	1.26 (0.71) 193
BMI: mean (SD) <i>n</i>	28.07 (4.94) 260	27.72 (4.88) 257
Killip Index (post-MI): mean (SD) <i>n</i>	1.12 (0.37) 124	1.09 (0.34) 111
No. of vessels treated by PTCA: mean (SD) <i>n</i>	1.24 (0.48) 96	1.18 (0.46) 105
No. of vessels treated by CABG: mean (SD) <i>n</i>	2.74 (0.93) 31	3.05 (1.54) 20

TABLE 6 Response rates to physical activity questionnaires at 6, 9 and 12 weeks

Time point (weeks)	Home-based: n (%) ^a	Centre-based: n (%) ^a	All: n (%)
6	188 (71.8)	181 (69.1)	369 (70.3)
9	184 (70.0)	174 (66.4)	358 (68.2)
12	170 (64.6)	172 (65.6)	342 (65.1)

^a There is no significant difference in the proportion of responders from home- and centre-based groups at any of the three time points.

TABLE 7 Characteristics of responders and non-responders to 6-, 9- and 12-week questionnaire

	Responders ^a (n = 452)	Non-responders (n = 73)
Allocation group		
Home-based	230 (50.9)	33 (45.2)
Hospital-based	222 (49.1)	40 (54.8)
Male: n (%)	346 (76.5)	56 (76.7)
Age: mean (SD)	61.9 (10.5)	55.63 (11.0)
Ethnicity: n (%)		
White	373 (82.5)	45 (61.6)
Asian	65 (14.4)	23 (31.5)
Other	14 (3.1)	5 (6.8)
Living alone: n (%)	66 (14.6)	10 (13.7)
Access to a car: n (%)	354 (78.3)	57 (78.1)
Years in full-time education: mean (SD)	10.4 (3.4)	11.1 (3.5)
In paid employment: n (%)	181 (40)	39 (53.4)
Diagnosis: n (%)		
MI	222 (49.1)	36 (49.3)
PTCA	181 (40.0)	30 (41.1)
CABG	49 (10.8)	7 (9.6)
Past medical history: n (%)		
Hypertension	211 (47.7)	35 (47.9)
MI	85 (18.9)	12 (16.4)
CABG	25 (5.6)	1 (1.4)
PTCA (angioplasty)	42 (9.4)	6 (8.2)
Attendance at CR	54 (12.0)	8 (11.1)
Diabetes	55 (12.3)	16 (21.9)
Smoking history: n (%)		
Current smoker at heart attack	149 (33.0)	30 (41.1)
Ex-smoker	185 (40.9)	22 (30.1)
Lifetime non-smoker	118 (26.1)	21 (28.8)
Baseline cardiac risk factors		
Physical activity: Godin score: mean (SD)	6.5 (3.9)	5.67 (3.2)
HADS anxiety score: mean (SD)	7.28 (4.2)	9.15 (4.9)
HADS depression score: mean (SD)	4.71 (3.2)	5.62 (3.8)
BMI: mean (SD)	27.55 (4.1)	28.69 (4.8)
SBP: mean (SD)	123.48 (17.4)	125.66 (19.9)
DBP: mean (SD)	72.15 (10.9)	72.90 (10.31)
TC: mean (SD)	4.75 (1.3)	4.75 (1.3)
6-month physical activity		
Physical activity: Godin score: mean (SD) n	6.97 (3.9) 432	6.85 (4.6) 48
Distance on ISWT: mean (SD) n	411.3 (174.6) 352	423.5 (150.0) 37

^a Responded to at least one questionnaire at 6, 9 or 12 weeks.

TABLE 8 Comparison of Godin score at 6 months in non-responders to physical activity questionnaires at 6, 9 and 12 weeks and responders with differing activity levels

Physical activity self-report at 6, 9 or 12 weeks	Physical activity score at 6 months: mean (SD) n		
	6 weeks	9 weeks	12 weeks
Low activity (<3× per week)	5.1 (3.55) 76	5.0 (3.6) 70	4.9 (3.6) 66
Moderate activity (3–4× per week)	7.1 (3.7) 208	6.7 (3.5) 188	6.5 (3.6) 137
High activity (≥5× per week)	9.2 (4.2) 72	9.5 (3.9) 84	9.1 (3.7) 111
Non-responder	6.5 (3.9) 121	6.7 (4.2) 135	6.8 (3.9) 163

TABLE 9 Proportion of respondents reporting at least three episodes of physical activity in the previous week at 6, 9 and 12 weeks

Time point (weeks)	Home-based: n (%)	Centre-based: n (%)	p-Value
6	177 (95.2)	154 (85.1)	0.01
9	170 (93.9)	155 (90.6)	0.2 (ns)
12	146 (90.1)	155 (93.4)	0.3 (ns)

ns, not significant.

TABLE 10 Physical activity score^a by rehabilitation group at 6, 9 and 12 weeks

	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value ^b (adjusted)
All^c					
6 weeks (n = 349)	4.78 (3.1)	4.32 (2.9)	4.0 (3, 6)	3.0 (3, 5)	0.2
9 weeks (n = 340)	5.17 (2.8)	4.55 (2.9)	5.0 (3, 7)	3.0 (3, 6)	0.01
12 weeks (n = 320)	6.06 (3.9)	5.60 (3.4)	5.0 (3, 8)	5.0 (3, 7)	0.3
Women^d					
6 weeks (n = 80)	4.34 (3.2)	3.56 (2.5)	3.0 (3, 5)	3.0 (2, 4.5)	0.2
9 weeks (n = 79)	4.38 (3.3)	4.09 (2.8)	3.0 (3, 5.75)	3.0 (3, 5)	0.7
12 weeks (n = 70)	5.14 (3.8)	4.60 (2.7)	4.0 (3, 8)	5.0 (3, 5.75)	0.8
Ethnic minority participants^e					
6 weeks (n = 52)	4.17 (2.7)	3.28 (2.7)	4.0 (2.75, 5)	3.0 (1, 5)	0.08
9 weeks (n = 52)	5.10 (2.7)	3.08 (2.2)	5.0 (3, 7)	3.0 (1, 5)	0.006
12 weeks (n = 46)	4.88 (2.5)	3.86 (2.7)	5.0 (3, 7)	4.0 (2, 5)	0.1
Older participants (≥70 years)^f					
6 weeks (n = 92)	4.40 (3.3)	3.35 (2.8)	3.0 (3, 5)	3.0 (2, 4)	0.03
9 weeks (n = 94)	4.30 (2.5)	4.06 (3.5)	3.0 (3, 5.25)	3.0 (3, 5)	0.5
12 weeks (n = 88)	4.67 (3.0)	4.65 (3.0)	4.0 (3, 7)	4.0 (2, 5)	0.8

IQR, interquartile range.
^a Scores weighted for intensity, max. score 18.
^b Mann–Whitney test.
^c Mann–Whitney adjusted for age, sex and ethnic group.
^d Mann–Whitney adjusted for age and ethnic group.
^e Mann–Whitney adjusted for age and sex.
^f Mann–Whitney adjusted for sex and ethnic group.

Self-reported quality of life as measured by the SF-12 was similar in participants in the home- and centre-based arms. The GMS also showed very similar results for both groups (Table 18). Neither scores had baseline values, so we were not able to evaluate change over time.

The home-based arm participants had had more cardiac events in the first 6 months, both adverse events (MI and death) and revascularisation procedures. These differences were not statistically significant (Table 19).

TABLE 11 Adherence data: hours of self-reported activity^a at 6, 9 and 12 weeks weighted for intensity

	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value ^b (adjusted)
All^c					
6 weeks (n = 349)	16.12 (15.0)	14.17 (19.6)	10.5 (6, 21)	9 (3, 17)	0.01
9 weeks (n = 340)	17.35 (15.7)	15.77 (20.3)	13 (7, 23)	11.5 (4, 20)	0.04
12 weeks (n = 320)	23.26 (22.1)	18.69 (19.3)	16 (9, 30)	13 (6, 25)	0.02
Women^d					
6 weeks (n = 80)	18.76 (14.7)	14.79 (19.8)	14 (8, 29)	11 (4, 16)	0.05
9 weeks (n = 79)	14.61 (13.1)	13.37 (11.0)	11 (4, 21)	12 (4, 20)	0.9
12 weeks (n = 70)	20.94 (16.7)	16.69 (13.5)	15.5 (8, 29)	12 (6.25, 25.75)	0.2
Ethnic minority participants^e					
6 weeks (n = 52)	9.64 (7.4)	8.54 (15.0)	7.5 (4, 14)	3 (1, 11.25)	0.02
9 weeks (n = 52)	13.43 (10.9)	9.22 (15.0)	10 (5, 18.75)	4 (1, 8)	0.005
12 weeks (n = 46)	19.04 (22.6)	15.73 (29.4)	12 (9, 20)	4.5 (2, 17)	0.02
Older participants (≥70 years)^f					
6 weeks (n = 92)	13.7 (13.5)	10.52 (11.0)	10 (6, 14)	8.5 (3, 14)	0.2
9 weeks (n = 94)	12.9 (10.3)	13.50 (13.4)	12 (5, 18)	10 (4, 20)	0.8
12 weeks (n = 88)	14.8 (10.0)	16.60 (13.7)	14 (6, 20.5)	14 (7, 21)	0.8

^a Scores weighted for intensity (moderate intensity ×2, vigorous intensity ×3).
^b Mann-Whitney test.
^c Mann-Whitney adjusted for age, sex and ethnic group.
^d Mann-Whitney adjusted for age and ethnic group.
^e Mann-Whitney adjusted for age and sex.
^f Mann-Whitney adjusted for sex and ethnic group.

TABLE 12 Adherence to the hospital-based programmes: percentage of sessions attended

	Mean sessions attended (%)	SD	n
All	55.7	46.5	255
Hospital			
1	42.6	44.6	92
2	72.2	43.0	101
3	42.3	48.3	39
4	58.7	45.1	23
Gender			
Male	56.4	46.7	194
Female	53.3	46.3	61
Ethnicity			
White	56.4	46.8	203
Non-white	53.8	45.4	51
Age (years)			
<50	42.2	47.9	36
50–69	58.6	45.2	149
≥70	56.4	48.1	70

Within-group differences at 6 months

Participants in the home-based arm of the study had significant improvements in the HADS anxiety score, TC, HDL-cholesterol and smoking prevalence from baseline to follow-up. The HADS

TABLE 13 Reasons for loss to clinical follow-up and absence of shuttle test at 6 months^a

	Home-based (n = 65)	Centre-based (n = 71)
DNA/withdrawn	13 (20.0)	20 (28.2)
Home visit	17 (26.2)	18 (25.4)
High cardiac risk for exercise test	17 (26.2)	22 (31.0)
Physical disability	14 (21.5)	9 (12.7)
Refused shuttle test	1 (1.5)	0
Died	3 (4.6)	2 (2.8)

^a Seven participants who did not attend (DNA) follow-up were abroad for prolonged periods. Home visits were undertaken for some participants who were too unwell to travel to the hospitals, or reluctant to attend.
 $\chi^2 = 4.1, p = 0.5.$

depression score did not change. As there was no ISWT at baseline, this was not included (Table 20). A similar picture was seen for the centre-based arm, although there was not a significant improvement in HDL-cholesterol (Table 21). In both arms the SBP and DBP rose significantly from baseline to follow-up, possibly explained in part by hypotension resulting from the cardiac event at baseline.

TABLE 14 Primary outcome measures at 6 months

	Home-based: mean (SD) n	Centre-based: mean (SD) n	Mean difference ^a	95% CI of mean difference	Adjusted mean difference ^b	95% CI of adjusted mean difference
SBP (mmHg)	133.34 (18.86) 245	133.73 (20.58) 238	-0.39	-3.91 to 3.14	0.18	-2.83 to 3.19
DBP (mmHg)	77.39 (13.83) 244	77.35 (15.95) 238	0.04	-2.63 to 2.71	0.63	-1.09 to 2.35
TC (mmol/l)	3.91 (0.85) 247	3.87 (0.88) 237	0.04	-0.11 to 0.20	0.03	-0.11 to 0.16
HDL-cholesterol (mmol/l)	1.28 (0.39) 247	1.31 (0.39) 238	-0.02	-0.09 to 0.05	0.03	-0.04 to 0.10
HADS anxiety score	6.76 (4.27) 241	6.26 (4.52) 233	0.51	-0.29 to 1.30	0.02	-0.60 to 0.65
HADS depression score	4.83 (4.00) 242	4.65 (3.58) 236	0.18	-0.50 to 0.87	0.09	-0.50 to 0.68
Distance on ISWT (m)	408.6 (168.2) 198	417.4 (175.4) 191	-11.32	-45.3 to 22.6	-12.8	-41.0 to 15.4
Smoking prevalence: n (%)	58 (23.9%)	48 (20.2%)	3.7%	-3.9 to 11.3%	RR of smoking in home 0.95	0.49 to 1.85

^a A positive score indicates a higher value in the home-based arm compared with the centre-based arm.

^b Adjusted for baseline score, age, sex, diagnosis, ethnicity and centre, except for the ISWT, which had no baseline score.

^c Cotinine validated; home-based arm has lower adjusted RR because of a higher prevalence of smoking at baseline.

TABLE 15 Comparison of self-reported shortness of breath or chest pain at 6-month follow-up in home- and centre-based groups

Symptoms ^a	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value ^b
Shortness of breath on movement	1.0 (1.2)	1.0 (1.2)	1 (0, 2)	1 (0, 2)	0.9
Shortness of breath at rest	0.40 (0.8)	0.43 (0.9)	0 (0, 1)	0 (0, 0)	0.5
Chest pain on movement	0.70 (1.0)	0.63 (1.0)	0 (0, 1)	0 (0, 1)	0.3
Chest pain at rest	0.64 (0.9)	0.5 (0.9)	1 (0, 1)	0 (0, 1)	0.05

^a Scaled from 0 to 4, with higher score indicating more symptoms.

^b Mann-Whitney test.

TABLE 16 Comparison of self-reported diet at 6-month follow-up in home- and centre-based groups

Food ^a	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value ^b
Serving of fruit or vegetables	3.45 (1.2)	3.64 (1.2)	3 (3, 4)	4 (3, 5)	0.04
Serving of fish (not fried)	1.54 (0.8)	1.62 (0.8)	2 (1, 2)	2 (1, 2)	0.29
Serving of chicken or turkey	1.86 (0.8)	1.84 (0.8)	2 (2, 2)	2 (2, 2)	0.8
Any fried food	4.94 (0.8)	4.90 (0.8)	5 (4, 5)	5 (4, 5)	0.5
Red meat, processed meat and meat pies	4.51 (0.9)	4.53 (0.9)	4 (4, 5)	4 (4, 5)	1.0
Snacks: chocolate, crisps, biscuits	4.46 (1.2)	4.45 (1.0)	5 (4, 5)	5 (4, 5)	0.5

^a Scaled from 0 to 6, with higher score indicating healthier diet.
^b Mann-Whitney test.

TABLE 17 Comparison of self-reported physical activity at 6-month follow-up in home- and centre-based groups

	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR) n	Centre-based: median (IQR) n	Mean difference (95% CI)
Physical activity score					
Baseline	6.21 (3.76)	6.04 (3.82)	6 (3, 9)	7 (3, 9)	0.17 (-0.48 to 0.83)
6 months	6.96 (3.81)	6.99 (4.14)	6 (3, 7)	7 (4, 9)	-0.03 (-0.74 to 0.69)
Hours of self-reported activity weighted for intensity					p-Value^a
Baseline	22.7 (25.1)	20.0 (20.9)	14.0 (7, 26) 213	14.0 (6, 25) 215	0.5
6 months	16.4 (17.0)	18.1 (25.4)	11.0 (6, 20) 234	11.0 (5, 20) 227	0.8

^a Mann-Whitney test.

TABLE 18 Quality of life at 6 months in home- and centre-based groups

	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value ^a
Global mood score					
Positive	19.89 (7.6)	19.93 (7.2)	20 (14, 25)	20 (15, 26)	0.8
Negative	12.85 (9.1)	12.12 (8.6)	11 (5, 19.25)	10 (6, 18)	0.5
SF-12					
PCS	42.28 (10.9)	42.56 (10.8)	41.96 (33.1, 53.1)	43.82 (33.8, 52.5)	0.8
MCS	49.19 (10.1)	50.33 (9.6)	50.83 (40.4, 57.8)	52.28 (43.6, 57.8)	0.3

MCS, mental component score; PCS, physical component score.
^a Mann-Whitney test.

TABLE 19 New cardiac events at 6-month follow-up in home- and centre-based groups

	Home-based: n (%)	Centre-based: n (%)	p-Value
MI	7 (2.7)	3 (1.1)	0.3
PTCA	27 (10.3)	19 (7.3)	0.3
CABG	2 (0.8)	1 (0.4)	0.6
Death	3 (1.1)	2 (0.8)	1.0
Any event	32 (13.2)	22 (9.6)	0.2

Significant improvements in self-reported diet and physical activity as measured by the Godin score occurred in both arms from baseline (Tables 22 and 23). The hours of self-reported physical activity fell.

Levels of satisfaction with the cardiac rehabilitation were generally high. More of the participants in the home-based arm found the written materials too simple, but this did not reach statistical significance (Table 24).

Twelve-month study outcomes

Completeness of data

Follow-up data were collected on 475 (91.5%) live participants at 12 months. Participants who were lost to follow-up were younger, had spent more years in education, were more likely to be smokers at baseline, reported a lower level of physical activity and had a higher HADS depression score and BMI at baseline (Table 25). Of those who were followed up, 99 (26.5%) did not do an ISWT for a variety of reasons, including being at too high a cardiac risk for exercise testing and co-morbidity (Table 26). Participants who were followed up without an ISWT were more likely to be female, to lack access to a car, to have a history of hypertension, to have been a smoker at study entry and to have higher anxiety and depression scores on the HADS than those who did the ISWT (Table 27).

Primary outcomes

ITT analysis of the primary outcomes revealed no difference at the 12-month follow-up for SBP, DBP, TC, HDL-cholesterol, the HADS scores, distance

TABLE 20 Within-group differences in primary outcomes at 6 months: home-based programme

	Baseline: mean (SD) n	6 months follow-up: mean (SD) n	Difference ^a	95% CI	p-Value
SBP	123.8 (17.3) 242	133.7 (18.7) 242	9.91	7.47 to 12.35	<0.001
DBP	72.3 (11.1) 241	77.6 (13.8) 241	5.30	3.49 to 7.10	<0.001
HADS anxiety score	7.82 (4.5) 233	6.7 (4.28) 233	-1.12	-1.6 to -0.63	<0.001
HADS depression score	4.86 (3.35) 239	4.86 (4.01) 239	0.004	-0.44 to 0.45	0.99
TC	4.76 (1.26) 243	3.91 (0.86) 243	-0.85	-1.01 to 0.68	<0.001
HDL-cholesterol	1.2 (0.56) 203	1.3 (0.4) 203	0.12	0.07 to 0.17	0.04
Smoking: n (%) N	87 (35.8%) 243	58 (23.9%) 243	-11.8	-19.9 to -3.7	<0.001

^a A positive result indicates an increase in the mean value from baseline to follow-up.

TABLE 21 Within-group differences in primary outcomes at 6 months: hospital-based programme

	Baseline: mean (SD) n	6 months follow-up: mean (SD) n	Difference ^a	95% CI	p-Value
SBP	123.8 (18.6) 235	134.0 (20.5) 235	10.14	7.72 to 12.56	<0.001
DBP	72.2 (10.4) 235	77.5 (15.9) 235	5.25	3.27 to 7.23	<0.001
HADS anxiety score	7.15 (4.19) 229	6.24 (4.51) 229	-0.9	-1.41 to -0.4	0.001
HADS depression score	4.68 (3.22) 230	4.61 (3.57) 230	-0.07	-0.53 to 0.39	0.76
TC	4.76 (1.37) 225	3.88 (0.88) 225	-0.89	-1.05 to 0.72,	<0.001
HDL-cholesterol	1.26 (0.73) 177	1.29 (0.39) 177	-0.02	-0.09 to 0.13	0.69
Smoking: n (%) N	85 (32.4%) 262	48 (20.2%) 238	-12.2	-20.0 to 4.4	<0.001

^a A positive result indicates an increase in the mean value from baseline to follow-up.

TABLE 22 Within-group differences in secondary outcomes at 6 months: home-based programme

	Baseline: mean (SD)	6-months: mean (SD)	Baseline: median (IQR)	6 months: median (IQR)	p-Value ^b
Self-reported diet^a					
Serving of fruit or vegetables	3.42 (1.2)	3.45 (1.2)	4 (3, 4)	3 (3, 4)	0.7
Serving of fish (not fried)	1.37 (0.9)	1.54 (0.8)	1 (1, 2)	2 (1, 2)	0.001
Serving of chicken or turkey	1.83 (0.8)	1.86 (0.8)	2 (2, 2)	2 (2, 2)	0.2
Any fried food	4.50 (1.1)	4.94 (0.8)	5 (4, 5)	5 (4, 5)	<0.001
Red meat, processed meat and meat pies	4.20 (0.9)	4.51 (0.9)	4 (4, 5)	4 (4, 5)	<0.001
Snacks: chocolate, crisps, biscuits	3.81 (1.4)	4.47 (1.2)	4 (3, 5)	5 (4, 5)	<0.001
Physical activity					
Hours of physical activity (weighted)	22.69 (25.1)	16.36 (1.0)	14.0 (7, 26)	11.0 (6, 20)	0.005
Physical activity score	6.22 (3.8)	6.96 (3.8)	6 (3, 9)	7 (3, 9)	0.01 ^c

^a Scaled from 0 to 6, with higher score indicating healthier diet.

^b Wilcoxon signed rank test.

^c Paired t-test.

TABLE 23 Within-group differences in secondary outcomes at 6 months: hospital-based programme

	Baseline: mean (SD)	6-months: mean (SD)	Baseline: median (IQR)	6 months: median (IQR)	p-Value ^b
Self-reported diet^a					
Serving of fruit or vegetables	3.52 (1.2)	3.6 (1.2)	4 (2.75, 4)	4 (3, 5)	0.2
Serving of fish (not fried)	1.52 (0.9)	1.62 (0.8)	2 (1, 2)	2 (1, 2)	0.07
Serving of chicken or turkey	1.81 (0.8)	1.84 (0.8)	2 (1, 2)	2 (2, 2)	0.6
Any fried food	4.69 (1.0)	4.90 (0.8)	5 (4, 5)	5 (4, 5)	0.03
Red meat, processed meat and meat pies	4.22 (1.0)	4.53 (0.9)	4 (4, 5)	4 (4, 5)	<0.001
Snacks: chocolate, crisps, biscuits	3.84 (1.3)	4.45 (1.0)	4 (3, 5)	5 (4, 5)	<0.001
Physical activity					
Hours of physical activity (weighted)	19.99 (20.9)	18.10 (25.4)	14 (6, 25)	11 (5, 20)	0.02
Physical activity score	6.04 (3.8)	6.99 (4.1)	6 (3, 7)	7 (4, 9)	0.006 ^c

^a Scaled from 0 to 6, with higher score indicating healthier diet.

^b Wilcoxon signed rank test.

^c Paired t-test.

TABLE 24 Experience of the rehabilitation programmes

	Home-based: n (%)	Centre-based: n (%)	Mann-Whitney Z-score	p-Value
Satisfaction with cardiac rehabilitation			-0.11	0.9
Very satisfied	95 (39.1)	92 (39.8)		
Quite satisfied	97 (39.9)	86 (37.2)		
Neutral	19 (7.8)	30 (13.0)		
Somewhat dissatisfied	7 (2.9)	9 (3.9)		
Very dissatisfied	25 (10.3)	14 (6.1)		
Support received post-event			-0.38	0.7
Too much	26 (10.7)	27 (11.5)		
About right	214 (88.1)	206 (87.7)		
Not enough	3 (1.2)	2 (0.9)		
Information given post-event			-0.97	0.4
Too much	20 (8.3)	20 (8.4)		
About right	216 (89.3)	217 (91.6)		
Not enough	6 (2.5)	0		
Written material given			-1.7	0.08
Too complicated	5 (2.1)	4 (1.8)		
About right	211 (90.6)	210 (95.5)		
Too simple	17 (7.3)	6 (2.7)		

walked on the ISWT or smoking cessation. When the analysis was adjusted for the randomising variables (age, sex, diagnosis, ethnicity and centre) and baseline value, there continued to be no significant differences (*Table 28*).

Sensitivity analysis

Missing values analysis was undertaken for the distance walked on the ISWT, which had 29% of missing data from live participants at 12 months, the SBP, DBP, TC and HADS anxiety and depression scores, which had 11–15% of missing data. Re-analysis with the imputed values did not alter the interpretation of the results. Re-analysis with the imputed values for the ISWT reduced the differences between the study groups, with an adjusted difference walked on the shuttle test of -16.0 m (95% CI -34.8 to 2.9). The differences in the HADS scores after imputation were also reduced: adjusted mean difference for HADS anxiety score 0.31 (95% CI -0.38 to 1.0) and for the HADS depression scores -0.16 (95% CI -0.77 to 0.44). Larger mean differences were seen in the analysis of blood pressure using the imputed data: for SBP mean difference 2.61 mmHg (95% CI -0.63 to 5.85), for DBP 0.86 mmHg (95% CI -0.79 to 2.52) and for TC 0.09 mmol/l (95% CI -0.04 to 0.22).

In these analyses, the centre-based group is always the reference group, so that negative differences indicate that the home-based group mean was less than the centre-based mean and positive

differences indicate that the home-based group mean was greater than the centre-based mean.

Secondary outcomes

Self-reported chest pain and shortness of breath at rest and shortness of breath on movement were similar in both the home- and centre-based groups, although participants in the home-based arm reported slightly more chest pain on movement (*Table 29*).

There was no difference in self-reported diet at 12 months (*Table 30*).

Self-reported physical activity (modified Godin score) was similar in the two groups, as were the hours of physical activity reported (*Table 31*).

Self-reported quality of life as measured by the SF-12 revealed that the physical component score was 42.3 (SD 11.1) in the home-based arm and 41.6 (SD 11.4) in the centre-based arm, mean difference 0.69 (95% CI -1.5 to 2.9). The mental component score was 50.5 (SD 9.6) in the home-based arm and 50.8 (SD 10.1) in the centre-based arm, mean difference -0.34 (95% CI -2.3 to 1.6). These scores were very similar to those reported at the 6-month follow-up.

The higher event rate in the home-based arm participants was maintained throughout the first 12 months, both adverse events (MI and death) and revascularisation procedures. However, the

TABLE 25 Baseline characteristics of participants followed up or lost to follow-up at 12 months

	Followed up at 12 months	No follow-up
Male: <i>n</i> (%)	369 (76.9)	31 (75.6)
Age: mean (SD) (years)	61.3 (10.7)	56.0 (11.1) ^a
Ethnicity: <i>n</i> (%)		
White	372 (79.5)	32 (78.0)
Asian	89 (17.1)	7 (17.1)
Other	16 (3.4)	2 (4.9)
Trial allocation to home	235 (50.2)	19 (46.3)
Living alone: <i>n</i> (%)	69 (14.7)	7 (17.1)
Access to a car: <i>n</i> (%)	370 (79.1)	29 (70.7)
Years in full-time education: mean (SD)	10.4 (3.4)	11.6 (2.6) ^a
In paid employment: <i>n</i> (%)	196 (41.9)	29 (48.8)
Diagnosis: <i>n</i> (%)		
MI	226 (48.3)	25 (61.0)
PTCA	189 (40.4)	15 (36.6)
CABG	53 (11.3)	1 (2.4)
Past medical history: <i>n</i> (%)		
Hypertension	216 (47.1)	20 (48.8)
MI	84 (18.0)	8 (19.5)
CABG	24 (5.2)	2 (4.9)
PTCA (angioplasty)	43 (9.3)	3 (7.3)
Attendance at CR	54 (11.6)	6 (14.6)
Diabetes	59 (12.7)	9 (22.0)
Smoking history: <i>n</i> (%)		
Current smoker at heart attack	150 (44.6)	23 (63.9) ^a
Healthy food intake: mean (SD)		
Fruit and vegetables	3.48 (1.2)	3.30 (1.1)
Fish	1.45 (0.9)	1.29 (1.0)
White meat	1.81 (0.8)	2.02 (0.8)
Unhealthy food intake: mean (SD)		
Fried food	4.62 (1.0)	4.27 (1.4)
Beef	4.23 (0.9)	4.03 (1.1)
Snacks	3.79 (1.4)	4.02 (1.5)
Physical activity score: mean (SD)	6.25 (3.8)	4.93 (3.4) ^a
HADS anxiety score: mean (SD)	7.48 (4.4)	7.83 (4.5)
HADS depression score: mean (SD)	4.71 (3.3)	5.83 (3.5) ^a
Clinical indices		
All patients SBP: mean (SD)	124.10 (18.0)	122.77 (13.8)
All patients DBP: mean (SD)	72.37 (10.9)	73.07 (9.2)
TC: mean (SD)	4.80 (1.3)	4.83 (1.2)
HDL-cholesterol: mean (SD)	1.18 (0.3)	1.21 (0.4)
BMI: mean (SD)	27.52 (4.1)	29.10 (4.4) ^a

^a Significant difference between groups ($p < 0.05$).

TABLE 26 Reasons for loss to clinical follow-up and absence of shuttle test at 12 months^a

	Home-based (<i>n</i> = 71)	Centre-based (<i>n</i> = 81)
DNA/withdrawn	22 (31.0)	25 (30.9)
Home visit	17 (23.9)	23 (28.4)
High cardiac risk for exercise test	14 (19.7)	17 (21.0)
Physical disability	12 (16.9)	12 (14.8)
Refused shuttle test	3 (4.2)	1 (1.2)
Died	3 (4.2)	3 (3.7)

^a Seven participants who did not attend follow-up were abroad for prolonged periods. Home visits were undertaken for some participants who were too unwell to travel to the hospitals, or reluctant to attend. Some patients completed a questionnaire, but did not attend for clinical assessment or accept a home visit.

TABLE 27 Baseline characteristics of participants with and without an ISWT result at 12 months

	ISWT	No ISWT
Male: <i>n</i> (%)	298 (80.5)	100 (67.1) ^a
Age: mean (SD) (years)	60.4 (10.3)	62.4 (11.7)
Ethnicity: <i>n</i> (%)		
White	290 (78.4)	124 (83.2)
Asian	69 (18.6)	18 (12.1)
Other	11 (3.0)	7 (4.7)
Trial allocation to home	191 (51.6)	69 (46.3)
Living alone: <i>n</i> (%)	52 (14.1)	24 (16.1)
Access to a car: <i>n</i> (%)	30 (83.0)	100 (67.1) ^a
Years in full-time education: mean (SD)	10.5 (3.4)	10.5 (3.2)
Employed: <i>n</i> (%)	53 (35.6)	166 (44.8)
Diagnosis: <i>n</i> (%)		
MI	175 (47.3)	80 (53.7)
PTCA	153 (41.4)	56 (37.6)
CABG	42 (11.4)	13 (8.7)
Past medical history: <i>n</i> (%)		
Hypertension	160 (44.0)	81 (55.5) ^a
MI	63 (17.1)	33 (22.3)
CABG	17 (4.6)	9 (6.1)
PTCA (angioplasty)	35 (9.6)	12 (8.1)
Attendance at CR	42 (11.4)	19 (12.8)
Diabetes	42 (11.5)	26 (17.4)
Smoking history: <i>n</i> (%)		
Current smoker at heart attack	112 (42.9)	67 (55.8) ^a
Healthy food intake: mean (SD)		
Fruit and vegetables	3.47 (1.2)	3.47 (1.2)
Fish	1.46 (0.9)	1.39 (0.8)
White meat	1.82 (0.8)	1.85 (0.7)
Unhealthy food intake: mean (SD)		
Fried food	4.60 (1.0)	4.6 (1.2)
Beef	4.2 (1.0)	4.2 (0.9)
Snacks	3.8 (1.3)	3.8 (1.4)
Physical activity score: mean (SD)	6.5 (4.0)	5.3 (3.2) ^a
HADS anxiety score: mean (SD)	7.27 (4.23)	8.19 (4.7) ^a
HADS depression score: mean (SD)	4.46 (3.2)	5.72 (3.6) ^a
Clinical indices		
All patients SBP: mean (SD)	123.51 (17.6)	124.42 (18.2)
All patients DBP: mean (SD)	72.71 (11.0)	71.21 (10.2)
TC: mean (SD)	4.76 (1.3)	4.83 (1.2)
HDL-cholesterol: mean (SD)	1.18 (0.31)	1.19 (0.36)
BMI: mean (SD)	27.46 (4.0)	28.30 (4.7)

^a Significant difference between the groups ($p < 0.05$).

total proportions of participants who had an event was small, with 16.2% of participants in the home-based arm and 12.1% of the centre-based participants having had an event. These differences were not statistically significant (Table 32).

Within-group changes

Participants in the home-based arm of the study had significant improvements in the HADS anxiety score, TC, HDL-cholesterol and smoking prevalence from baseline to follow-up. The HADS depression score improved, but not significantly.

TABLE 28 Primary outcome measures at 12 months

	Home-based: mean (SD) n	Centre-based: mean (SD) n	Mean difference ^a	95% CI of mean difference	Adjusted mean difference ^b	95% CI of adjusted mean difference
SBP (mmHg)	133.55 (18.37) 235	132.18 (21.54) 232	1.37	-2.27 to 5.01	1.94	1.11 to 5.00
DBP (mmHg)	74.94 (9.82) 235	74.21 (10.66) 232	0.73	-1.13 to 2.59	0.42	-1.25 to 2.09
TC (mmol/l)	3.99 (0.90) 232	3.88 (0.83) 233	0.11	-0.05 to 0.26	0.10	-0.05 to 0.24
HDL-cholesterol (mmol/l)	1.29 (0.39) 233	1.33 (0.62) 233	-0.01	-0.08 to 0.06	0.05	-0.01 to 0.11
HADS anxiety score	6.37 (4.67) 220	5.94 (4.44) 226	0.43	-0.40 to 1.26	-0.02	-0.69 to 0.65
HADS depression score	4.60 (3.97) 225	4.77 (3.66) 229	-0.17	-0.88 to 0.53	-0.35	-0.95 to 0.25
Distance on ISWT (m)	391.3 (162.11) 191	407.4 (157.6) 179	-15.52	-48.18 to 17.13	-21.5	-48.27 to 5.24
Smoking prevalence: n (%)	49 (21.5%)	45 (19.5%)	2.0%	-5.3 to 9.3%	RR of being a smoker in home 0.9 ^c	0.5 to 1.85

^a A positive score indicates a higher value in the home-based arm compared with the centre-based arm.

^b Adjusted for baseline score, age, sex, diagnosis, ethnicity and centre, except for the ISWT, which had no baseline score.

^c Home-based arm had a lower adjusted RR of smoking due to a higher prevalence of smoking at baseline.

TABLE 29 Comparison of self-reported shortness of breath or chest pain at 12-month follow-up in home- and centre-based groups

Symptoms ^a	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value
Shortness of breath on movement	1.03 (1.1)	0.95 (1.1)	1 (0, 2)	1 (0, 1)	0.4
Shortness of breath at rest	0.41 (0.9)	0.45 (1.0)	0 (0, 0)	0 (0, 0)	0.7
Chest pain on movement	0.69 (1.0)	0.51 (0.9)	0 (0, 1)	0 (0, 1)	0.04 ^b
Chest pain at rest	0.57 (1.0)	0.43 (0.8)	0 (0, 1)	0 (0, 1)	0.2

^a Scaled from 0 to 4, with higher score indicating more symptoms.

^b Home-based arm has a higher rank for the two significant results; therefore, the home-based patients experienced more symptoms.

TABLE 30 Comparison of self-reported diet at 12-month follow-up in home- and centre-based groups

Self-reported diet ^a	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value
Serving of fruit or vegetables	3.45 (1.2)	3.58 (1.2)	3 (3, 4)	4 (3, 4)	0.4
Serving of fish (not fried)	1.53 (0.8)	1.54 (0.8)	2 (1, 2)	2 (1, 2)	0.8
Serving of chicken or turkey	1.78 (0.8)	1.85 (0.7)	2 (1, 2)	2 (2, 2)	0.3
Any fried food	4.83 (0.8)	4.85 (0.8)	5 (4, 5)	5 (4, 5)	0.9
Red meat, processed meat and meat pies	4.57 (0.9)	4.5 (0.8)	4 (4, 5)	4 (4, 5)	0.8
Snacks: chocolate, crisps, biscuits	4.47 (1.0)	4.4 (1.1)	5 (4, 5)	4 (4, 5)	0.5

^a Scaled from 0 to 6, with higher score indicating healthier diet.

TABLE 31 Comparison of self-reported physical activity at 12-month follow-up in home- and centre-based groups

Physical activity	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value
Physical activity score	7.11 (4.0)	6.83 (4.1)	7.0 (3, 9)	7.0 (3, 9)	0.4 ^a
Hours of self-reported activity weighted for intensity	19.24 (20.8)	15.91 (16.7)	12.0 (5.5, 27.6)	10.5 (5, 20.6)	0.3 ^b

^a Independent samples t-test.
^b Mann-Whitney test.

TABLE 32 Patients with new cardiac events at 12-month follow-up in home- and centre-based groups

	Home-based: n (%)	Centre-based: n (%)	p-Value
Myocardial infarction			
1 × MI	7 (3.2%)	3 (1.4%)	0.2
2 × MI	2 (0.9%)	1 (0.5%)	
Revascularisation			
1 × revascularisation	30 (14.0%)	25 (12.1%)	0.1
2 × revascularisations	6 (2.8%)	1 (0.5%)	
Death	3 (1.1%)	3 (1.1%)	1.0
Any event	38 (19.2%) ^a	28 (14.5%) ^b	0.2

^a 5 people reported 2 events, 2 people had 3 events and 1 person had 4 events.
^b 3 people reported 2 events.

TABLE 33 Within-group differences in primary outcomes at 12 months: home-based programme

	<i>n</i>	Baseline: mean (SD)	12 months follow-up: mean (SD)	Difference ^a	95% CI	<i>p</i> -Value
SBP	232	124.0 (17.3)	133.8 (18.3)	9.72	7.4 to 12.1	<0.001
DBP	232	72.3 (11.2)	75.0 (9.8)	2.64	1.3 to 4.0	<0.001
HADS anxiety score	212	7.91 (4.5)	6.35 (4.5)	-1.56	-2.07 to -1.05	<0.001
HADS depression score	222	4.85 (3.3)	4.61 (4.0)	0.24	-0.23 to 0.71	0.3
TC	228	4.76 (1.28)	3.99 (0.90)	-0.77	-0.94 to -0.61	<0.001
HDL-cholesterol	192	1.17 (0.28)	1.30 (0.39)	0.13	0.08 to 0.18	<0.001
Smoking: <i>n</i> (%)	263	94 (35.7%)	49 (21.5%)	-14.2%	-22.4 to -6.0	<0.001

^a A positive result indicates an increase in the mean value from baseline to follow-up.

TABLE 34 Within-group differences in primary outcomes at 12 months: hospital-based programme

	<i>n</i>	Baseline: mean (SD)	12 months follow-up: mean (SD)	Difference ^a	95% CI	<i>p</i> -Value
SBP	229	124.1 (18.8)	132.5 (21.5)	8.36	5.8 to 10.96	<0.001
DBP	229	72.3 (10.5)	74.3 (10.7)	2.01	0.54 to 3.5	0.008
HADS anxiety score	223	7.12 (4.14)	5.91 (4.4)	-1.22	-1.75 to -0.68	<0.001
HADS depression score	224	4.53 (3.13)	4.73 (3.6)	0.21	-0.23 to 0.64	0.4
TC	221	4.83 (1.31)	3.90 (0.83)	-0.93	-1.09 to -0.77	<0.001
HDL-cholesterol	171	1.20 (0.34)	1.27 (0.34)	0.07	0.04 to 0.11	<0.001
Smoking: <i>n</i> (%)	262	85 (32.4%)	45 (19.5%)	12.9%	-20.8 to -5.0	<0.001

^a A positive result indicates an increase in the mean value from baseline to follow-up.

Of those who smoked at baseline, 43.6% reported quitting. As there was no ISWT at baseline, this was not included (Table 33). A similar picture was seen for the centre-based arm, although there was no reduction in the HADS depression score (Table 34). In both arms the SBP and DBP rose significantly from baseline to follow-up.

Significant improvements in self-reported diet occurred in both arms from baseline, although improvement in diet occurred for more food types in the home-based arm. Physical activity as measured by the modified Godin score improved in both arms from baseline (Tables 35 and 36). The hours of self-reported physical activity fell.

Interactions and subgroup analysis

Interactions analysis was undertaken to determine whether any prespecified subgroups (defined by gender, age, ethnic status, initial diagnosis, centre and self-reported adherence) had differing results for the home- versus centre-based analyses of the primary outcomes. This revealed a significant

difference ($p < 0.01$) in SBP at 12 months between participants randomised to the home- and centre-based arms following MI or a revascularisation procedure. Participants who were post-MI had a lower mean SBP at 12 months in the home- than centre-based arm and post-revascularisation patients had a lower SBP in the centre-based arm. A similar picture was seen for DBP, but this did not reach statistical significance ($p = 0.04$). No interactions with study group were seen for ethnic group, age group or gender for any of the primary outcomes (Table 37).

Two-year study outcomes

Follow-up data were collected on 461 (89%) live participants and the status (alive/deceased) of all but 12 participants was obtained at the 2-year follow-up point.

As at the other prespecified time points, we were unable to detect any significant differences between the home- and centre-based groups for any of the primary outcomes (SBP, DBP,

TABLE 35 Within-group differences in secondary outcomes at 12 months: home-based programme

	Baseline: mean (SD)	12 months: mean (SD)	Baseline: median (IQR)	12 months: median (IQR)	p-Value ^b
Self-reported diet^a					
Serving of fruit or vegetables	3.42 (1.2)	3.45 (1.2)	4 (3, 4)	3 (3, 4)	0.5
Serving of fish (not fried)	1.37 (0.9)	1.53 (0.8)	1 (1, 2)	2 (1, 2)	0.01
Serving of chicken or turkey	1.83 (0.8)	1.78 (0.8)	2 (2, 2)	2 (1, 2)	0.3
Any fried food	4.50 (1.1)	4.83 (0.8)	5 (4, 5)	5 (4, 5)	<0.001
Red meat, processed meat and meat pies	4.20 (0.9)	4.57 (0.9)	4 (4, 5)	4 (4, 5)	<0.001
Snacks: chocolate, crisps, biscuits	3.81 (1.4)	4.47 (1.0)	4 (3, 5)	5 (4, 5)	<0.001
Physical activity					
Hours of physical activity (weighted)	22.69 (25.1)	19.24 (20.8)	14.0 (7, 26)	12.0 (5.5, 27.6)	0.01
Physical activity score	6.22 (3.8)	7.11 (4.0)	6.0 (3, 9)	7.0 (3, 9)	0.02 ^c

^a Scaled from 0 to 6, with higher score indicating healthier diet.

^b Wilcoxon signed rank test.

^c Paired t-test.

TABLE 36 Within-group differences in secondary outcomes at 12 months: hospital-based programme

	Baseline: mean (SD)	12 months: mean (SD)	Baseline: median (IQR)	12 months: median (IQR)	p-Value ^b
Self-reported diet^a					
Serving of fruit or vegetables	3.52 (1.2)	3.58 (1.2)	4 (2.75, 4)	4 (3, 4)	1.0
Serving of fish (not fried)	1.52 (0.9)	1.54 (0.8)	2 (1, 2)	2 (1, 2)	0.8
Serving of chicken or turkey	1.81 (0.8)	1.85 (0.7)	2 (1, 2)	2 (2, 2)	0.4
Any fried food	4.69 (1.0)	4.85 (0.8)	5 (4, 5)	5 (4, 5)	0.3
Red meat, processed meat and meat pies	4.22 (1.0)	4.54 (0.8)	4 (4, 5)	4 (4, 5)	<0.001
Snacks: chocolate, crisps, biscuits	3.84 (1.3)	4.40 (1.1)	4 (3, 5)	4 (4, 5)	<0.001
Physical activity					
Hours of physical activity (weighted)	20.0 (20.9)	15.91 (16.7)	14 (6, 25)	10.5 (5, 20.6)	0.008
Physical activity score	6.04 (3.82)	6.82 (4.08)	6 (3, 7)	7 (3, 9)	0.01 ^c

^a Scaled from 0 to 6, with higher score indicating healthier diet.

^b Wilcoxon signed rank test.

^c Paired t-test.

TABLE 37 *p*-Values for interaction tests between the rehabilitation programme and age, gender, ethnic group, diagnosis, centre and self-reported adherence

Interaction	SBP	DBP	TC	HDL-cholesterol	HADS anxiety score	HADS depression score	ISWT
Initial diagnosis ^a and treatment	<0.01	0.04	0.9	0.3	0.6	0.6	0.6
Ethnic group ^b and treatment	0.2	0.5	0.4	0.1	0.04	0.2	0.5
Gender and treatment	0.6	0.4	0.7	0.6	0.6	0.7	0.4
Age group ^c and treatment	0.3	0.3	0.3	0.6	0.5	0.7	0.7
Hospital 2 or 1 and treatment	<0.05	0.1	1.0	0.7	0.4	0.5	0.25
Hospitals 3/4 or 1 and treatment	0.06	0.05	0.8	0.7	1.0	0.7	0.6
Adherence ^d and treatment	0.3	0.8	0.6	0.9	0.1	0.01	0.02

^a MI or revascularisation.
^b White or ethnic minority.
^c Aged under 75 or 75+ years.
^d Self-reported physical activity score at 9 weeks of <3 or 3+.

cholesterol, HADS, distance walked on ISWT and smoking) (Table 38). However, the width of the CIs indicates that there might have been clinically significant differences that we failed to identify by chance.

There was no difference in the total number of events (MI/revascularisations/all-cause mortality) between the home- and centre-based groups. The overall number of events was small, but there were more MIs and deaths in the home-based group, although this was not statistically significant (Table 39).

Levels of self-reported shortness of breath and chest pain, diet and physical activity scores were similar between the two arms of the study (Tables 40–42).

Repeated measures analysis of primary outcomes

Repeated measures analysis did not find a significant effect between the home- and centre-based groups for any of the primary outcome measures across the four assessment time points. In addition, there was no treatment group time interaction for any of the primary outcomes. For SBP, DBP, TC, HDL-cholesterol and the ISWT there were significant effects over time. Table 43 details the differences for the periods from baseline to 6-month follow-up, 6–12 months and 12–24 months. Only the HADS depression score showed no change over time. The largest changes occurred in the first 6 months of the study, with an improvement in TC, HDL-cholesterol, HADS

anxiety score and smoking rates. A significant rise in both SBP and DBP occurred in the first 6 months.

Figures 2–9 display the unadjusted primary outcome measures over time for the home- and centre-based groups.

Centre effect

The centre-based CR programmes differed from each other in frequency and total number of sessions prescribed. It is possible that small effects between centre- and home-based programmes might have occurred which were not detected in the interactions analysis, due to small numbers in each centre. It is possible that in comparison with the least intensive centre-based programme, home-based CR would be more effective, but the most intensive centre-based programme would be more effective than home-based.

The results are presented for each centre (with centres 3 and 4 combined), comparing outcomes from the home- and centre-based programmes. Hospitals 3 and 4 were combined because the same staff provided both CR programmes and there was considerable movement between the two hospitals, with a patient potentially admitted to Hospital 4, transferred to Hospital 3 for a cardiac catheterisation, recruited in Hospital 3, but choosing to attend rehabilitation at Hospital 4.

The self-reported physical activity during the CR period is shown for each hospital of recruitment for the centre- and home-based programmes.

TABLE 38 Primary outcome measures at 24 months

	Home-based: mean (SD) n	Centre-based: mean (SD) n	Mean difference ^a	95% CI of mean difference	Adjusted mean difference ^b	95% CI of adjusted mean difference
SBP (mmHg)	131.71 (16.82) 225	130.86 (19.24) 227	0.85	-2.49 to 4.20	0.55	-2.42 to 3.51
DBP (mmHg)	73.78 (9.68) 224	73.02 (10.7) 228	0.76	-1.13 to 2.65	0.57	-1.33 to 2.48
TC (mmol/l)	4.09 (1.01) 223	3.98 (0.85) 224	0.11	-0.06 to 0.29	0.11	-0.06 to 0.28
HDL-cholesterol (mmol/l)	1.32 (0.33) 223	1.35 (0.46) 224	-0.03	-0.11 to 0.04	0.02	-0.04 to 0.09
HADS anxiety score	6.20 (4.34) 223	6.04 (4.39) 228	0.15	-0.66 to 0.96	-0.34	-1.0 to 0.33
HADS depression score	4.63 (3.72) 224	4.84 (3.60) 229	-0.22	-0.89 to 0.46	-0.35	-0.94 to 0.23
Distance on ISWT (m)	363.5 (168.3) 179	355.3 (167.7) 163	8.24	-27.5 to 44.0	-8.25	-36.6 to 20.1
Smoking prevalence: n (%)	52 (22.9%)	48 (20.7%)	2.2%	-5.25 to 9.65	RR of being a smoker in home 0.86 ^c	0.03 to 1.71

^a A positive score indicates a higher value in the home-based arm compared with the centre-based arm.

^b Adjusted for baseline score, age, sex, diagnosis, ethnicity and centre, except for the ISWT, which had no baseline score.

^c Home-based arm had a lower adjusted RR of smoking due to a higher prevalence of smoking at baseline.

TABLE 39 Cardiac events in patients by 2-year follow-up in home- and centre-based groups

	Home-based: n (%)	Centre-based: n (%)	p-Value
Myocardial infarction ^a			
1 × MI	8 (4.0)	4 (2.0)	
2 × MI	3 (1.5)	0	0.2
3 × MI	0	1 (0.5)	
PTCA ^a			
1 × PTCA	27 (13.4)	30 (15.4)	0.4
2 × PTCA	10 (5.0)	5 (2.6)	
CABG ^a	4 (2.0)	6 (3.1)	0.4
Death	6 (2.3)	3 (1.1)	0.3
Any event	39 (20.1) ^b	39 (20.5) ^c	1.0

^a Self-reported events.

^b 6 people reported 2 events, 3 reported 3 events, 1 reported 4 events and 1 reported 5 events.

^c 4 people reported 2 events and 2 reported 3 events.

TABLE 40 Comparison of self-reported shortness of breath or chest pain at 24-month follow-up in home- and centre-based groups

Symptoms ^a	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value
Shortness of breath on movement	1.06 (1.18)	0.86 (1.01)	1 (0, 2)	1 (0, 1)	0.06
Shortness of breath at rest	0.45 (0.86)	0.35 (0.77)	0 (0, 1)	0 (0, 0)	0.2
Chest pain on movement	0.54 (0.89)	0.45 (0.77)	0 (0, 1)	0 (0, 1)	0.4
Chest pain at rest	0.44 (0.80)	0.39 (0.78)	0 (0, 1)	0 (0, 0)	0.6

^a Scaled from 0 to 4, with higher score indicating more symptoms.

TABLE 41 Comparison of self-reported diet at 24-month follow-up in home- and centre-based groups

Self-reported diet ^a	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value
Serving of fruit or vegetables	3.31 (1.17)	3.43 (1.23)	3 (3, 4)	3 (3, 4)	0.2
Serving of fish (not fried)	1.50 (0.74)	1.54 (0.78)	2 (1, 2)	2 (1, 2)	0.4
Serving of chicken or turkey	1.74 (0.80)	1.81 (0.76)	2 (1, 2)	2 (1, 2)	0.4
Any fried food	4.87 (0.74)	4.86 (0.77)	5 (4, 5)	5 (4, 5)	0.9
Red meat, processed meat and meat pies	4.50 (0.82)	4.56 (0.83)	4 (4, 5)	4 (4, 5)	0.6
Snacks: chocolate, crisps, biscuits	4.38 (1.04)	4.30 (0.83)	4 (4, 5)	4 (4, 5)	0.4

^a Scaled from 0 to 6, with higher score indicating healthier diet.

TABLE 42 Comparison of self-reported physical activity at 24-month follow-up in home- and centre-based groups

Physical activity	Home-based: mean (SD)	Centre-based: mean (SD)	Home-based: median (IQR)	Centre-based: median (IQR)	p-Value
Physical activity score	6.81 (4.05)	6.69 (4.10)	7 (3, 9)	7 (3, 9)	0.8 ^a
Hours of self-reported activity weighted for intensity	18.93 (18.44)	16.64 (16.39)	14 (7, 23)	12 (5, 22)	0.9 ^b

^a Independent samples t-test.
^b Mann-Whitney test.

TABLE 43 Mean change in primary outcomes for different periods: baseline to 6 months, 6 to 12 months and 12 to 24 months

	Baseline to 6 months		6 to 12 months		12 to 24 months	
	Mean change	95% CI	Mean change	95% CI	Mean change	95% CI
SBP (mmHg)	10.03	8.31 to 11.74	-0.65	-2.21 to 0.91	-1.63	-3.19 to -0.07
DBP (mmHg)	3.62	2.6 to 4.6	-1.09	-0.2 to 2.0	-1.16	-1.99 to -0.34
TC (mmol/l)	-0.90	-1.0 to -0.78	0.02	-0.04 to 0.08	0.13	0.06 to 0.20
HDL-cholesterol (mmol/l)	0.11	0.07 to 0.14	-0.01	-0.05 to 0.02	0.05	0.02 to 0.08
HADS anxiety score	-1.01	-1.36 to -0.66	-0.45	-0.74 to -0.17	0.07	-0.22 to 0.35
HADS depression score	-0.036	-0.35 to 0.28	-0.01	-0.28 to 0.26	-0.02	-0.28 to 0.23
Distance on ISWT (m)	NA	-	-22.7	-33.7 to -11.7	-29.6	-39.4 to -19.8

NA, not applicable.

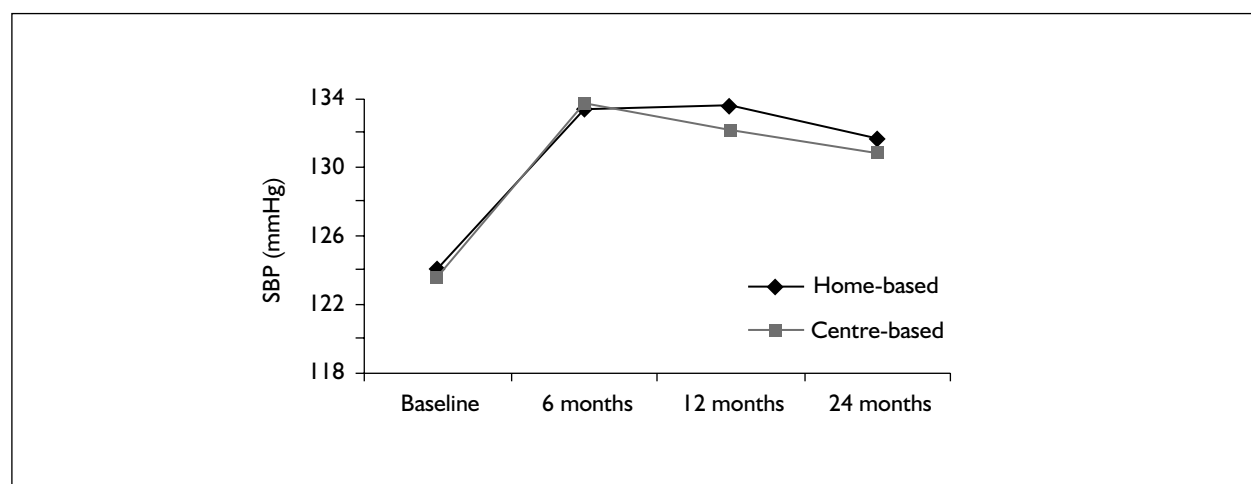


FIGURE 2 Mean systolic blood pressure at assessment points for home- and centre-based groups

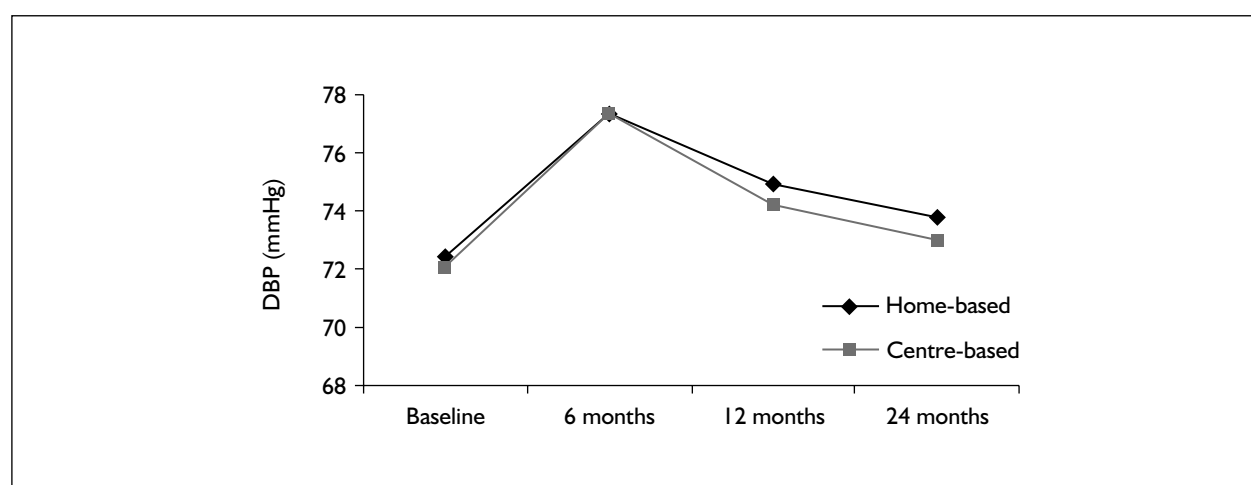


FIGURE 3 Mean diastolic blood pressure at assessment points for home- and centre-based groups

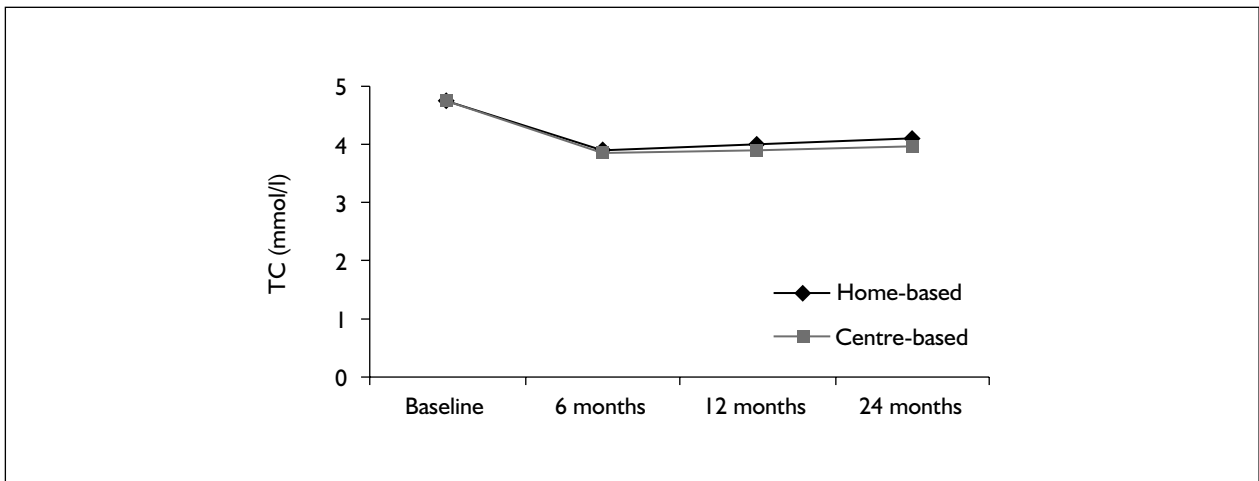


FIGURE 4 Mean total cholesterol at assessment points for home- and centre-based groups

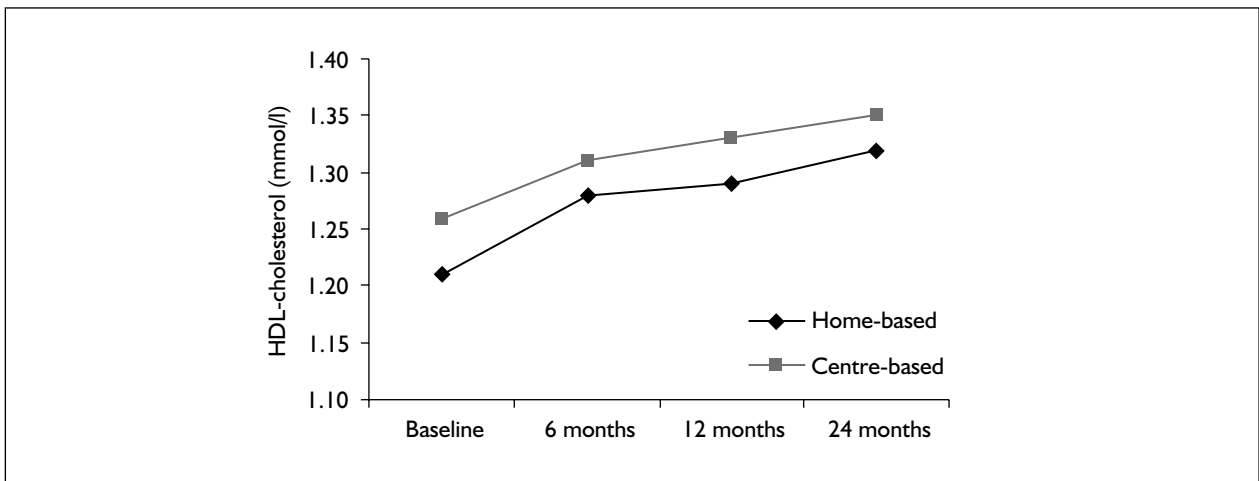


FIGURE 5 Mean HDL-cholesterol at assessment points for home- and centre-based groups

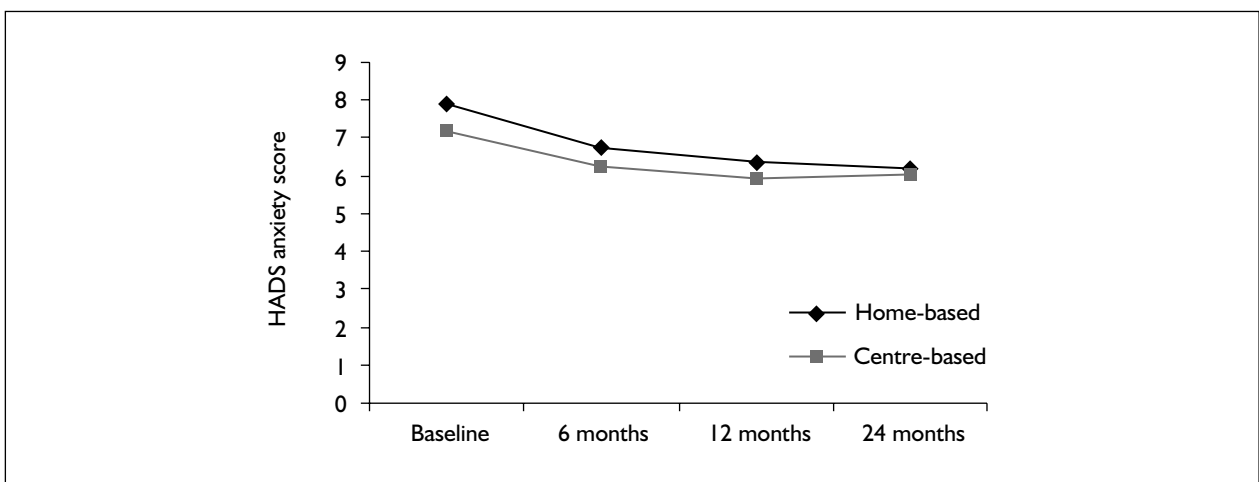


FIGURE 6 Mean HADS anxiety score at assessment points for home- and centre-based groups

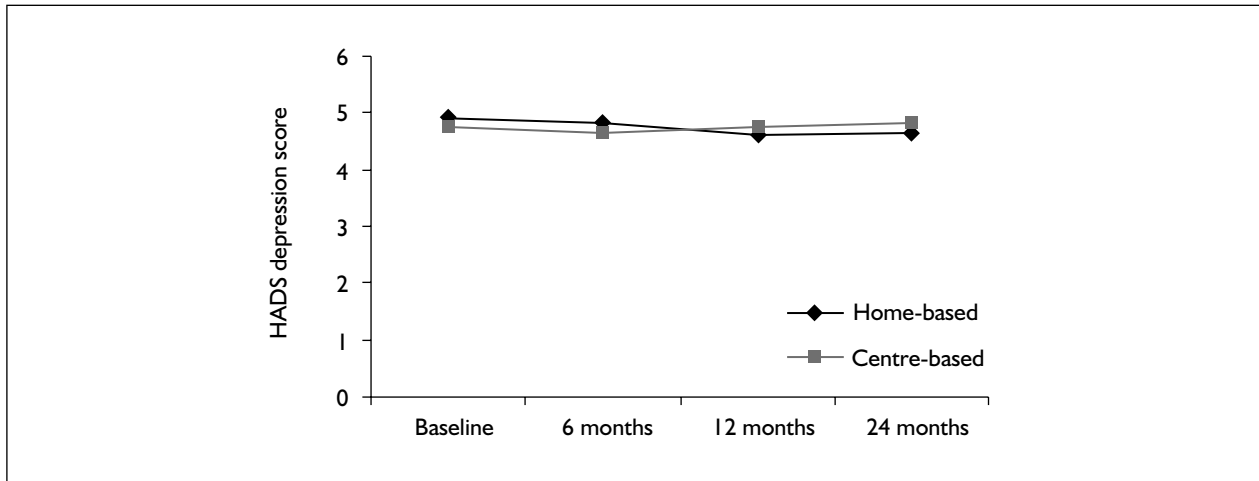


FIGURE 7 Mean HADS depression score at assessment points for home- and centre-based groups

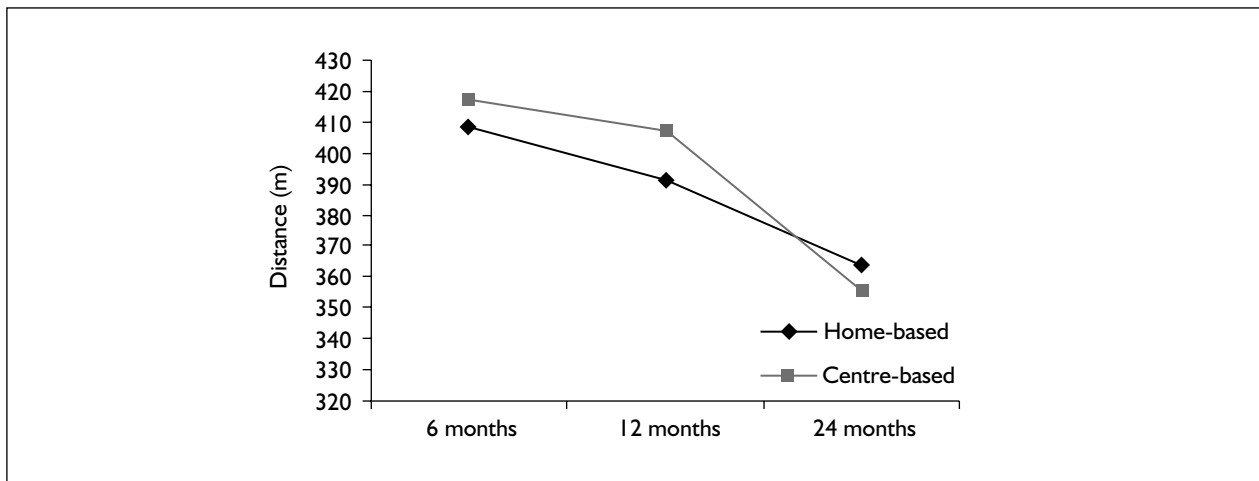


FIGURE 8 Mean distance walked on ISWT for home- and centre-based groups

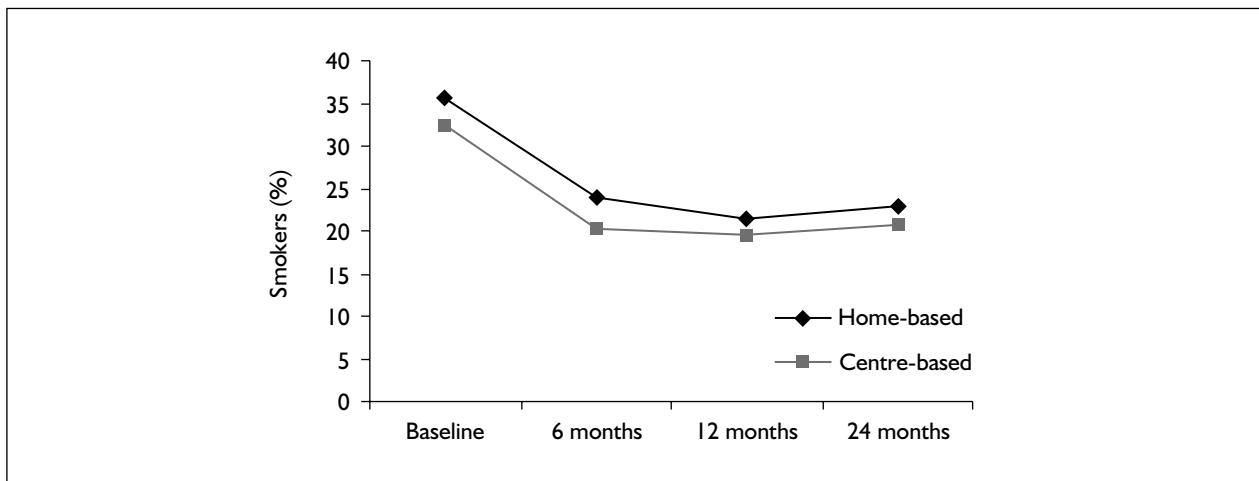


FIGURE 9 Smoking prevalence at assessment points for home- and centre-based groups

TABLE 44 Self-reported physical activity during rehabilitation period, by centre of recruitment

Recruitment centre	Home-based		Centre-based	
	Median	IQR	Median	IQR
6 weeks				
Hospital 1	4	3, 5	3	3, 5
Hospital 2	4	3, 6.5	3	3, 6.25
Hospitals 3 and 4	3	2.25, 5.75	4	2, 5
9 weeks				
Hospital 1	5	3, 7	3	2, 6
Hospital 2	5	3, 7	3	3, 6
Hospitals 3 and 4	5	3, 6	3	3, 6
12 weeks				
Hospital 1	5	3, 8	5	4, 7
Hospital 2	6	3, 8	5	3, 9
Hospitals 3 and 4	5	2, 9	4.5	2, 7

For each hospital of recruitment, patients in the home-based programme reported more physical activity (Table 44).

There are differences at baseline in the primary outcome measures between the home- and centre-based arms for individual hospitals of recruitment, due to the smaller numbers in each group (Table 45). The primary outcomes at the 6-month follow-up are shown in Table 46. There were no statistically significant differences between the home- and centre-based arms for any primary outcome measures for any of the three hospitals of recruitment when adjusted analyses were done, accounting for differences in baseline variables. Interestingly, Hospital 1, which had the longest exercise programme in the centre-based arm, had the largest difference between the arms for the distance achieved on the ISWT, although this did not reach statistical significance.

At the 12-month follow-up, home-based participants recruited from Hospital 2, which had the least intensive hospital-based programme, had a significantly higher mean SBP and achieved a significantly lower distance on the ISWT (see Table 47 for details). By the 2-year follow-up there was only one significant difference between home- and centre-based arms for the three hospitals, namely that of TC in Hospitals 3 and 4 (Table 48).

Health service resource use

Health service use was collected by self-report for admissions to hospital for all causes and cardiovascular causes, day-case admissions and GP and practice nurse visits for their heart condition.

No significant differences were found between the home- and centre-based groups for any of these factors at any of the follow-up points (Table 49). Participants from both groups had similar periods off from work following their cardiac event and were in paid employment by the 2-year assessment (Table 50). The proportions of participants in each group who were taking the main groups of secondary preventive medications (beta-blockers, aspirin or anti-platelet medication and cholesterol-lowering medication) were not significantly different between groups (Table 51). The proportion of participants on an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-II receptor antagonist was 10% lower in the centre-based group at the 2-year follow-up ($p < 0.05$).

Economic analysis

This section reviews the outcomes and cost per patient data in order to assess the relative cost-effectiveness of the intervention, that is, the home-based arm compared with the centre-based arm. The results are discussed in terms of testing the study hypotheses (inference) and in Bayesian terms (estimation), with the latter estimating cost-effectiveness regardless of statistical significance. In summary, no statistically significant difference was found in relation to outcomes. Cost per patient was statistically significantly higher in the home-based arm, but this difference did not persist from a societal perspective. The home-based arm had a slightly worse QALY score at baseline, which persisted at 6, 12 and 24 months. Overall, adjusting for the baseline difference, the home-based arm had a slightly worse (but non-significant) outcome in QALYs.

Outcomes

The QALY values, shown in Table 52, show slightly higher values in the centre-based compared with the home-based arm, by 2.6% at baseline, 2.6% at 6 months, 2.0% at 12 months and 2.9% at 24 months. These differences were not statistically significant, but the home-based arm had slightly worse scores.

Costs

As no significant differences in NHS non-rehabilitation resource use or in employment status were hypothesised or observed, only rehabilitation services were costed. More participants in the centre-based arm reported the use of hospital maintenance and community rehabilitation (49 people versus 18 in the home-based arm), but as we did not have information on the duration of

TABLE 45 Primary outcome measures at baseline by centre

	Hospital 1			Hospital 2			Hospitals 3 and 4											
	Home-based		Centre-based	Home-based		Centre-based	Home-based		Centre-based									
	Mean	SD	n	Mean	SD	n	Mean	SD	n									
SBP (mmHg)	121.90	18.7	89	123.57	18.5	93	124.00	16.1	113	123.24	17.8	107	126.13	17.3	61	123.61	19.3	62
DBP (mmHg)	73.89	10.8	89	73.64	10.8	93	71.00	11.5	113	70.13	10.2	107	72.70	10.5	61	72.86	10.2	62
TC (mmol/l)	4.93	1.3	88	4.83	1.5	91	4.63	1.3	111	4.72	1.2	104	4.71	1.1	60	4.96	1.2	54
HDL-cholesterol (mmol/l)	1.16	0.3	81	1.23	0.4	76	1.18	0.3	92	1.20	0.3	78	1.20	0.4	44	1.11	0.3	39
HADS anxiety score	8.13	4.4	82	6.96	4.4	89	7.99	4.8	110	7.92	4.3	106	7.38	4.3	61	6.31	3.6	61
HADS depression score	4.98	3.3	87	4.48	3.2	89	5.03	3.7	112	5.24	3.4	104	4.62	3.0	61	4.34	3.0	62

TABLE 46 Primary outcome measures at 6-month follow-up by centre

	Hospital 1			Hospital 2			Hospitals 3 and 4											
	Home-based		Centre-based	Home-based		Centre-based	Home-based		Centre-based									
	Mean	SD	n	Mean	SD	n	Mean	SD	n									
SBP (mmHg)	130.24	19.6	84	132.74	20.2	85	134.02	17.1	106	135.15	21.0	95	136.77	20.6	55	132.9	20.6	58
DBP (mmHg)	75.63	10.4	84	75.59	10.7	85	75.38	10.2	105	75.09	11.1	95	78.48	13.9	55	75.2	10.9	58
TC (mmol/l)	3.92	0.9	86	3.68	0.8	86	3.91	0.8	106	3.93	0.9	95	3.92	0.8	55	4.1	0.9	56
HDL-cholesterol (mmol/l)	1.32	0.5	86	1.33	0.4	86	1.25	0.2	105	1.30	0.4	95	1.29	0.5	53	1.3	0.4	57
HADS anxiety score	7.31	3.9	81	6.10	4.4	81	6.56	4.4	106	6.66	4.6	95	6.35	4.5	54	5.8	4.6	57
HADS depression score	4.93	3.8	84	4.65	3.4	82	5.04	4.3	104	5.07	3.8	96	4.30	3.6	54	4.0	3.3	58
ISWT (m)	412.64	179.9	72	430.71	190.3	70	387.2	153.0	87	389.04	149.1	73	448.97	174.4	39	441.0	187.4	48

TABLE 47 Primary outcome measures at 12-month follow-up by centre

	Hospital 1			Hospital 2			Hospitals 3 and 4											
	Home-based		Centre-based	Home-based		Centre-based	Home-based		Centre-based									
	Mean	SD	n	Mean	SD	n	Mean	SD	n									
SBP (mmHg)	128.35	18.6	82	132.97	21.2	84	137.3 ^a	16.7	100	133.77 ^a	23.1	91	134.58	19.51	53	128.47	19.3	57
DBP (mmHg)	74.04	9.0	82	76.04	10.9	84	75.2	9.8	100	73.23	10.7	91	75.79	10.98	53	73.06	10.1	57
TC (mmol/l)	3.95	0.9	82	3.82	0.6	84	3.96	0.9	98	3.84	0.8	92	4.11	0.9	52	4.04	1.1	57
HDL-cholesterol (mmol/l)	1.31	0.3	82	1.30	0.3	84	1.29	0.4	99	1.32	0.3	92	1.24	0.5	52	1.25	0.3	57
HADS anxiety score	6.72	4.1	74	5.85	4.5	81	6.28	4.8	96	6.33	4.3	88	6.04	4.5	50	5.47	4.5	57
HADS depression score	4.38	3.0	78	4.72	3.7	83	5.10	4.8	96	5.16	3.8	90	4.00	3.5	51	4.23	3.3	56
ISWT (m)	391.7	159.1	69	410.0	144.2	68	367.6 ^a	154.5	82	394.2 ^a	145.7	69	439.3	175.4	40	425.0	195.1	42

^a *p* < 0.05 (adjusted for age, sex, diagnosis and baseline value except for ISWT, which had no baseline measurement).

TABLE 48 Primary outcome measures at 24-month follow-up by centre

	Hospital 1			Hospital 2			Hospitals 3 and 4											
	Home-based		Centre-based	Home-based		Centre-based	Home-based		Centre-based									
	Mean	SD	n	Mean	SD	n	Mean	SD	n									
SBP (mmHg)	129.76	18.8	79	130.96	17.8	81	133.13	15.5	98	133.43	22.0	90	132.03	16.1	48	126.58	15.6	56
DBP (mmHg)	73.09	9.8	79	73.83	9.8	81	73.38	11.3	98	72.56	10.4	90	75.68	9.6	48	72.63	9.8	56
TC (mmol/l)	4.19	1.2	77	3.96	0.8	79	4.07	0.9	98	4.13	0.9	89	4.00 ^a	0.8	48	3.79 ^a	0.8	56
HDL-cholesterol (mmol/l)	1.36	0.3	77	1.41	0.5	79	1.31	0.3	98	1.35	0.4	89	1.29	0.4	48	1.27	0.4	56
HADS anxiety score	6.38	4.1	76	5.74	4.4	82	6.31	4.6	99	6.57	4.6	89	5.67	4.3	48	5.67	4.0	57
HADS depression score	4.66	3.4	76	4.77	3.7	81	4.83	4.3	100	5.48	3.7	90	4.15	2.9	48	3.97	0.3	58
ISWT (m)	363.75	169.1	64	374.38	162.7	64	336.15	170.7	78	319.68	152.6	62	420.81	150.8	37	381.89	192.9	37

^a *p* < 0.05 (adjusted for age, sex, diagnosis and baseline value).

TABLE 49 Health service utilisation at follow-up by study group

	Home-based		Centre-based		p-Value ^a
	n	Mean (SD)	n	Mean (SD)	
Healthcare resource use from 0 to 6 months					
Admissions to hospital for cardiovascular disease	37	0.15 (0.46)	44	0.18 (0.52)	0.5
Admissions to hospital for all conditions	61	0.25 (0.61)	59	0.25 (0.59)	0.9
Nights in hospital for cardiovascular disease 0–6 months	176	0.73 (3.26)	172	0.72 (2.78)	0.4
Nights in hospital for all conditions	284	1.18 (4.57)	211	0.89 (2.97)	0.8
Day case admissions for heart condition	68	0.31 (0.72)	76	0.35 (0.88)	0.8
GP consultations for heart condition in last 3 months at 6 months	234	1.01 (1.37)	266	1.19 (1.73)	0.4
Practice nurse consultations for heart condition in last 3 months at 6 months	134	0.61 (1.75)	82	0.37 (0.93)	0.3
Healthcare resource use from 6 to 12 months					
Admissions to hospital for cardiovascular disease	20	0.17 (0.48)	29	0.21 (0.52)	0.3
Admissions to hospital for all conditions	38	0.08 (0.34)	49	0.12 (0.41)	0.3
Nights in hospital for cardiovascular disease	122	0.52 (3.09)	74	0.31 (1.60)	0.5
Nights in hospital for all conditions	218	0.92 (4.29)	144	0.59 (2.12)	0.4
Day case admissions for heart condition	31	0.14 (0.49)	41	0.19 (0.61)	0.5
GP consultations for heart condition in last 3 months at 12 months	144	0.65 (1.14)	158	0.72 (1.54)	0.8
Practice nurse consultations for heart condition in last 3 months at 12 months	74	0.33 (0.80)	65	0.30 (0.93)	0.7
Healthcare resource use from 12 to 24 months					
Admissions to hospital for cardiovascular disease	23	0.10 (0.34)	31	0.13 (0.41)	0.4
Admissions to hospital for all conditions	46	0.20 (0.45)	61	0.26 (0.57)	0.3
Nights in hospital for cardiovascular disease	120	0.53 (2.25)	141	0.61 (3.02)	0.4
Nights in hospital for all conditions	283	1.25 (4.61)	434	1.87 (7.43)	0.4
Day case admissions for heart condition	39	0.17 (0.52)	55	0.24 (1.0)	1.0
GP consultations for heart condition in last 3 months at 12 months	119	0.53 (1.14)	150	0.66 (1.42)	0.7
Practice nurse consultations for heart condition in last 3 months at 12 months	69	0.31 (0.67)	69	0.31 (0.68)	0.8

^a Mann–Whitney test.

TABLE 50 Employment status at follow-up periods by study group

Employment	Home-based	Centre-based	p-Value ^e
In paid employment prior to initial cardiac event: n (%)	109 (41.5)	111 (42.4)	1.0
Time off work (weeks): mean (SD)	9.01 (6.11)	8.96 (7.02)	0.4
Still off work at 6 months, if in paid employment prior to initial cardiac event: ^b n (%)	26 ^c (25.5)	20 ^d (20.2)	0.8
Not working at 12 months, if in paid employment prior to initial cardiac event: ^b n (%)	26 ^e (26.5)	24 ^f (25.3)	0.3
In employment at 2 years: ^b n (%)	72 (31.9)	68 (29.8)	

^a t-test (Mann-Whitney).
^b The denominators are the number of people in paid employment prior to the cardiac event for which they received CR. Denominators vary due to some loss to follow-up:
^c 102; ^d 99; ^e 98; ^f 95.

TABLE 51 Secondary preventive drug use at follow-up by study group

	Home-based: n (%)	Centre-based: n (%)	p-Value
On aspirin or antiplatelet drug			
At 6 months	234 (95.5)	234 (98.3)	0.08
At 12 months	227 (97.0)	226 (97.0)	1.0
At 24 months	214 (95.1)	220 (96.9)	0.3
On beta-blocker			
At 6 months	185 (75.5)	182 (76.5)	0.8
At 12 months	169 (72.2)	171 (73.4)	0.8
At 24 months	161 (71.6)	164 (72.2)	0.9
On ACE inhibitor or angiotensin-II receptor antagonist			
At 6 months	185 (75.5)	165 (69.3)	0.1
At 12 months	176 (75.2)	161 (69.1)	0.1
At 24 months	177 (78.7)	156 (68.7)	0.02
On cholesterol-lowering drug			
At 6 months	219 (89.4)	216 (90.8)	0.6
At 12 months	216 (92.3)	221 (94.8)	0.3
At 24 months	195 (86.7)	206 (90.7)	0.2

TABLE 52 EQ-5D results at baseline and 6-, 12- and 24-month follow-ups by treatment arm

	Home-based			Centre-based			Mean difference ^a	95% CI of mean difference	Adjusted mean difference ^b	95% CI of adjusted mean difference
	Mean	SD	n	Mean	SD	n				
Baseline	0.737	0.24	257	0.757	0.21	262	-0.020	-0.059 to 0.019	-0.018	-0.057 to 0.020
6 months	0.742	0.26	238	0.762	0.23	237	-0.020	-0.064 to 0.025	-0.016	-0.058 to 0.026
12 months	0.744	0.27	223	0.759	0.23	229	-0.016	-0.063 to 0.031	-0.010	-0.054 to 0.034
24 months	0.731	0.29	223	0.753	0.26	231	-0.022	-0.072 to 0.028	-0.019	-0.068 to 0.030

^a A positive score indicates a higher value in the home-based arm compared with the centre-based arm.
^b Adjusted for baseline score, age, sex, diagnosis, ethnicity and centre.

TABLE 53 Summary of unit costs (2002–3 prices) and sources of information^a

Unit cost	£/contact hour	£/non-contact hour
Hospital staff costs:		
CR nurse	50	23
Physiotherapist	39	
Dietician	39	
Exercise physiologist	39	
Clerk	23	23
Home staff costs:		
CR nurse	50	23
Staff travel costs	0.23/km	NHS mileage rate
Patient travel costs	0.30/km	AA Motoring Trust
Home equipment:		
The Heart Manual	20/copy	http://www.theheartmanual.com
Training	2/copy dispensed	Trial estimates, caseload 100
Patient costs:		
Missed earnings	5/h	Minimum wage

^a Sources: all Netten and Curtis,¹³⁴ except Heart Manual and travel costs, the sources of which are indicated in the table. The cost per contact hour was used in all instances except for nurse travel costs. The nurses employed in the study were on the same salaries as those used by Netten and Curtis.

their attendance, this was not included in the costing. Given the relatively low cost of these services, their omission is unlikely to affect the overall results. Rehabilitation costs comprised costing from the NHS perspective. To these were added the costs of patient travel (both direct costs and cost of travel time) to give the societal perspective. The mean cost per patient referred to CR in the home-based arm was £198 (95% CI £189 to £208), approximately 25% above that of the hospital arm of £157 (95% CI £139 to £175). Hence from an NHS perspective, the home-based arm was more costly than the hospital-based arm ($p < 0.05$). This difference was statistically significant. From a societal perspective, however, the inclusion of patient travel costs and travel time increased the mean cost of the hospital-based arm

to £181 (95% CI £159 to £203), such that, although the cost differential remained, it was no longer statistically significant. The unit costs used and hospital staffing levels are summarised in *Tables 53* and *54*.

Economic sensitivity analysis

One alternative scenario within the NHS perspective was costed for each arm. In the home-based arm, the duration of visits was limited to 30 minutes (the initial home visit had been costed at 40 minutes and subsequent visits at 30 minutes, based on nurse reports) and a maximum of three home visits allowed. Although this reduced the mean cost per patient, it remained significantly higher than the original mean cost of £157 in the hospital-based arm.

TABLE 54 Summary of centre-based rehabilitation session costs

Hospital	Duration	No. of patients ^a	Staff ^b	Occasional staff
1	3-h session (people attend part of this) up to 24 attendances	40	2 nurses, 2 sports physiologists, 1 clerk and 5 unpaid volunteers	None
2	9 sessions of 1 1/2 h	12	1 nurse (F or G-grade), 1 physiotherapist and 1 exercise technician	40 minutes from dietician every 9 weeks
3	8 sessions × 2 1/2 h and 4 sessions × 1 h	28 14	2 G-grade nurses, healthcare assistant, physiotherapist G-grade nurse + physiotherapist	1/2 h per 12-session course of pharmacist, dietician, smoking cessation advisor and occupational therapist
4	8 sessions × 2 h and 4 sessions × 1 h	20 10	2 nurses, physiotherapist and physiotherapy assistant 1 nurse and physiotherapist	1/2 h per 12-session course of pharmacist, dietician and occupational therapist

^a The programmes are rolling, so if someone drops out their place will be filled up by a newcomer within a week or two.
^b All nurses were costed as CR nurse in Table 53. Similarly, sports physiologist and exercise technician were costed as exercise physiologist, and healthcare assistant was costed the same as clerk.

TABLE 55 Mean costs of centre-based CR: NHS and societal perspectives

	n	NHS perspective (costs)		Societal perspective (costs)	
		Mean (£)	95% CI	Mean (£)	95% CI
All centres	225	156.7	138.6 to 174.8	181.5	203.4 to 159.6
Hospital 1	86	193.4	151.6 to 235.2	221.6	173.4 to 269.9
Hospital 2	98	149.8	131.4 to 168.1	177.7	150.4 to 205.1
Hospitals 3 and 4	61	115.0	87.3 to 114.7	130.8	98.5 to 163.2

The alternative scenario in the hospital-based arm allowed for an additional 1 hour for up to four staff in preparing for and clearing up after each rehabilitation session. This increased the mean cost from £114 to £151, closer to the original mean cost in the home-based arm of £165, although this difference remained statistically significant.

Inter-hospital variations

Tables 46–48 show how outcomes varied by each of the three hospital groups. Similar differences applied to the costs, as follows. Mean cost per session planned was broadly similar by hospital (range £14–16), but the cost per planned course varied more widely, with that of Hospital 1 costing roughly double that of the others (£380 versus

from £137–178). This was due to Hospital 1 planning 24 rehabilitation sessions compared with 9–12 for the other hospitals. However, the attendance rate was lower in Hospital 1 at 43% compared with 63% for the rest, thus reducing the difference in cost per course attended, with Hospital 1 having a higher cost than the other hospitals: at £193.4 (95% CI £151.6 to £235.2) from an NHS perspective and £221.6 (95% CI £173.4 to £269.9) from a societal perspective. This is similar to the cost of the home-based programme. Hospital 2 and Hospitals 3 and 4 had lower costs (Table 55). The difference between Hospital 1 and each of the other centres was statistically significant, but not between Hospitals 2 and Hospitals 3 and 4, as indicated by the 95% CIs.

TABLE 56 EQ-5D results at 12-month follow-up by treatment arm for the three hospital groups

Hospital	Home-based			Centre-based			Mean difference ^a	95% CI of mean difference	Adjusted mean difference ^b	95% CI of adjusted mean difference
	Mean	SD	n	Mean	SD	n				
1	0.756	0.22	77	0.743	0.25	83	0.012	-0.061 to 0.860	0.006	-0.068 to 0.080
2	0.702	0.31	95	0.769	0.23	89	-0.067	-0.147 to 0.014	-0.052	-0.128 to 0.024
3 and 4	0.803	0.25	51	0.768	0.23	57	0.036	-0.055 to 0.126	0.038	-0.034 to 0.111

^a A positive score indicates a higher value in the home-based arm compared with the centre-based arm.
^b Adjusted for baseline score, age, sex, diagnosis and ethnicity.

Although not statistically significant, *Table 56* shows that the QALYs at the 12-month follow-up by centre are no longer all in favour of the centre-based arm.

Cost of rehabilitation and other cardiac interventions

The costs of a range of cardiac interventions are given in Appendix 2.

Chapter 4

Results of qualitative studies

Individual interviews with non-adherers

Interviewees

Forty-nine patients were interviewed and a summary of patient characteristics is shown in *Table 57*; 28 were randomised to the hospital-based programme and 21 to the home-based programme. Five of the 21 home-based patients transferred to the hospital-based programme. Sixteen (33%) patients were female and 15 (31%) were from minority ethnic groups (nine south Asian, one black Caribbean, five white Irish). Twenty-seven (55%) were aged over 65 years and, of these, nine were in their 70s and two in their 80s. The average ages of patients in the home- and hospital-based groups were both 63 years, and in the male and female groups were also 63 years. This is similar to the mean age of patients in the trial (61 years). Patients in the minority ethnic groups were younger than those in the white British group (mean age 59 versus 66 years). At recruitment, 12 patients had a diagnosis of

post-MI with thrombolysis, 11 post-MI without thrombolysis, 22 post-PTCA and four post-CABG.

Results

Themes related to participation in CR emerging from the 49 interviews were grouped into five main areas, each with a range of subcategories: patient's experience of the NHS; knowledge and expectations of CR; health beliefs (including causes of heart disease, current health and lifestyle modification); barriers to participation; experience of CR.

Patients' reasons for not attending or not completing their CR programme were varied and no one reason emerged as a major factor (*Tables 58 and 59*). Reasons also varied between the home- and hospital-based programmes. Most patients gave several reasons for not completing their programme with one factor as the key factor. Two patients (P18 and P47) appeared unwilling to participate in their CR programme at all; however, patient P47 had gradually increased the distance

TABLE 57 Summary of characteristics of patients interviewed

	Home-based programme	Hospital-based programme
Total	21	28
Male	11	22
Female	10	6
Mean age at randomisation (range) (years):	62.6 (34–79)	63.2 (47–87)
Male <50	1	1
Male 50–60	3	8
Male 60–70	4	8
Male >70	3	5
Female <60	4	2
Female >60	6	4
Ethnic group:		
White British	15	19
White Irish	3	2
Indian	3	4
Pakistani	0	2
Black Caribbean	0	1
Recruitment diagnosis:		
post-MI with thrombolysis	4	8
post-MI without thrombolysis	4	7
post-PTCA	10	12
post-CABG	3	1
Previous CR experience	2	6

TABLE 58 Patients' reasons for non-adherence to home-based cardiac rehabilitation programme^a

Patient no.	M/F	Age (years)	Ethnicity ^b	Programme ^c	Personal		Health problems			Other activities			Programme-related reasons					Patients' reasons for non-adherence																				
					Not interested	Feeling well	No need to do rehabilitation	In denial about heart disease	Never done any exercises before	Personal/family problems	Returned to work	Carer	Too ill	Angina	Arthritis	Spondylitis, back pain, spinal degeneration	Difficulty walking		Leg pain on walking	Emphysema	Breathless	Heart failure	Waiting for surgery/treatment	Receiving disability allowance	Told to stop	Housework	Gardening	Shopping	Decorating	Doing more walking	Joined gym/alternative exercise class	Exercise bike/rowing machine at home	Playing football	Not motivated at home	Lack of supervision at home	Not invited to hospital session	Waiting for start date	Too far to hospital
P45	M	56	W1	h							×																											Still gets some angina on exertion but has bad rheumatoid arthritis in his knees and unable to exercise much. Did some exercises little at a time. Receives disability allowance
P31	M	58	W1	h							×																								School caretaker did exercises so he could return to work (tied house) but not fit enough. Has since had surgery for frozen shoulders and now doing physiotherapy for that. Doing some walking (dogs) but tires easily and still gets some chest pain			
P6	M	65	WB	h							×																								Positive about home-based programme. Stopped because one exercise gave him backache. Did a lot of walking but stopped due to bad legs. Keeps active with decorating			
P43	M	66	WB	h							×																								Well motivated ex-army fitness instructor and former England boxing coach. Did some exercises but now has difficulty walking due to severe pain from spinal problem and waiting for surgery			
P29	M	67	WB	h																															Totally unfit to do anything – has had oxygen installed in house. Had mild heart attack while doing home exercises			
P46	M	68	WB	h																															Diabetes diagnosed at time of heart attack and now also kidney disease. Did exercises for first few weeks but found it too tiring. Runs out of energy very quickly doing any activity due to diabetes			

continued

TABLE 58 Patients' reasons for non-adherence to home-based cardiac rehabilitation programme^a (cont'd)

Patient no.	M/F	Age (years)	Ethnicity ^b	Programme ^c	Personal			Health problems						Other activities						Programme-related reasons							Patients' reasons for non-adherence										
					In denial about heart disease	Never done any exercises before	Personal/family problems	Returned to work	Carer	Too ill	Angina	Arthritis	Spondylitis, back pain, spinal degeneration	Difficulty walking	Leg pain on walking	Empysema	Breathless	Heart failure	Waiting for surgery/treatment	Receiving disability allowance	Told to stop	Housework	Gardening	Shopping	Decorating	Doing more walking		Joined gym/alternative exercise class	Exercise bike/rowing machine at home	Playing football	Lack of supervision at home	Not invited to hospital session	Waiting for start date	Too far to hospital	Lack of parking at hospital	Time not convenient	Didn't like hospital sessions
P47	M	70	WB	h	X	X	X	X										X																			Not interested in CR programme at all (exercise or heart manual) – didn't need it. Now feeling 100%, playing golf twice a week and just returned from 2 months in Tasmania. Would not have done hospital-based programme either
P42	M	75	WB	h		X																												X	Bored at home so has part-time job. Did some exercises morning and evening but found motivation difficult and stopped as soon as BRUM nurse stopped coming. Does little walking		
P30	F	50	I	h		X																											X	Has never done any exercise so doesn't know what to expect or how to do it. Has 5 children and does all the housework which keeps her active during the day			
P3	F	52	WB	h		X																												X	In denial about heart attack. Says she has done some exercise but probably not much. Has joined a gym and stopped smoking		
P49	F	53	WB	h																														X	Did exercises for first few weeks, but recovered very quickly and was back to her normal routine so didn't see the need to in addition to her everyday activities (childminder). Goes to keep fit		
P33	F	61	WB	h																														X	Very confused about exercise programme. Said she had not done exercises because she did not go to hospital. Said she followed Heart Manual but probably did not. Does more walking		

continued

TABLE 58 Patients' reasons for non-adherence to home-based cardiac rehabilitation programme^a (cont'd)

Patient no.	M/F	Age (years)	Ethnicity ^b	Programme ^c	Patients' reasons for non-adherence			
					Personal	Health problems	Other activities	Programme-related reasons
P4	M	72	WB	hX	Not interested Feeling well No need to do rehabilitation In denial about heart disease Never done any exercises before Personal/family problems Returned to work Carer Too ill Angina Arthritis Spondylitis, back pain, spinal degeneration Difficulty walking Leg pain on walking Emphysema Breathless Heart failure Waiting for surgery/treatment Receiving disability allowance Told to stop Housework Gardening Shopping Decorating Doing more walking Joined gym/alternative exercise class Exercise bike/rowing machine at home Playing football Not motivated at home	Lack of supervision at home Not invited to hospital session Waiting for start date Too far to hospital Lack of parking at hospital Time not convenient Didn't like hospital sessions Other participants too old Exercises too easy Previous hospital CR experience	Patients' reasons for non-adherence Not motivated at home. Changed to hospital-based programme, which he completed. Continued at leisure centre but left due to arthritis in knees Unable to walk far as gets too exhausted. Uses electric cart to go out. Poorly motivated. Would probably not have done exercises even if she was more active. Said nurse did not call. Heavy smoker Lacked motivation to exercise at home. Social problems – going through divorce. Community psychiatric nurse encouraged her to go to hospital-based programme	
P26	F	53	WB	hX	Spondylitis, back pain, spinal degeneration Difficulty walking Leg pain on walking Emphysema Breathless Heart failure Waiting for surgery/treatment Receiving disability allowance Told to stop Housework Gardening Shopping Decorating Doing more walking Joined gym/alternative exercise class Exercise bike/rowing machine at home Playing football Not motivated at home	Not motivated at home Lack of supervision at home Not invited to hospital session Waiting for start date Too far to hospital Lack of parking at hospital Time not convenient Didn't like hospital sessions Other participants too old Exercises too easy Previous hospital CR experience		
P7	F	65	WB	hX	Personal/family problems Returned to work Carer Too ill Angina Arthritis Spondylitis, back pain, spinal degeneration Difficulty walking Leg pain on walking Emphysema Breathless Heart failure Waiting for surgery/treatment Receiving disability allowance Told to stop Housework Gardening Shopping Decorating Doing more walking Joined gym/alternative exercise class Exercise bike/rowing machine at home Playing football Not motivated at home	Not motivated at home Lack of supervision at home Not invited to hospital session Waiting for start date Too far to hospital Lack of parking at hospital Time not convenient Didn't like hospital sessions Other participants too old Exercises too easy Previous hospital CR experience		

^a X = reason for non-attendance/non-adherence; X = main reason.^b Ethnicity: WB = white British; I = Indian; P = Pakistani; BC = black Caribbean; WI = white Irish.^c Programme: h = home; H = hospital; hX = home crossover.

TABLE 59 Patients' reasons for non-adherence to hospital-based cardiac rehabilitation programme^a

Patient no.	M/F	Age (years)	Ethnicity ^b	Programme ^c	Personal		Health problems				Other activities				Programme-related reasons							Patients' reasons for non-adherence																
					Not interested	Feeling well	No need to do rehabilitation	In denial about heart disease	Never done any exercises before	Personal/family problems	Returned to work	Carer	Too ill	Angina	Arthritis	Spondylitis, back pain, spinal degeneration	Difficulty walking	Leg pain on walking	Emphysema	Breathless	Heart failure		Waiting for surgery/treatment	Receiving disability allowance	Told to stop	Housework	Gardening	Shopping	Decorating	Doing more walking	Joined gym/alternating exercise class	Exercise bike/rowing machine at home	Playing football	Not motivated at home	Lack of supervision at home	Not invited to hospital session	Waiting for start date	Too far to hospital
P17	M	47	WB	H										X			X							X											Impossible to park at hospital. Drove round looking for space on several occasions but gave up and after missing a few sessions he stopped going. Returned to work			
P24	M	50	W1	H			X		X																									Needs hip replacement. Unable to exercise. Walks with difficulty with a stick, social services installing bath lift and stair lift. Receives disability allowance				
P19	M	51	WB	H				X						X																			Back at work in physically demanding job. Works erratic shifts. Thought he was on home-based programme. Not invited. Does more walking					
P39	M	51	W1	H							X													X									Dropped out after several sessions as too far to travel by bus and didn't feel comfortable as mainly old people in CR group. Thought he could exercise at home but not motivated. Too breathless to return to work					
P41	M	51	WB	H										X												X							Said he wasn't invited to attend CR but also said that employer wouldn't allow time off as letter was on University and not hospital letterhead. Bought own rowing and running machines, attends local gym and does lots more walking					
P9	M	56	P	H							X																						Too ill. Has more blocked smaller arteries. Breathless. In constant pain					
P37	M	56	WB	H																											X	Hasn't been invited to exercise session. Has only done shuttle walk test						
P13	M	58	WB	H				X		X																							Too ill to exercise – has arthritis, spondylitis, in constant pain. Receives disability allowance					

continued

TABLE 59 Patients' reasons for non-adherence to hospital-based cardiac rehabilitation programme^a (cont d)

Patient no.	M/F	Age (years)	Ethnicity ^b	Programme ^c	Personal			Health problems										Other activities				Programme-related reasons									Patients' reasons for non-adherence						
					No need to do rehabilitation	In denial about heart disease	Never done any exercises before	Personal/family problems	Returned to work	Carer	Too ill	Angina	Arthritis	Spondylitis, back pain, spinal degeneration	Difficulty walking	Leg pain on walking	Emphysema	Breathless	Heart failure	Waiting for surgery/treatment	Receiving disability allowance	Told to stop	Housework	Gardening	Shopping	Decorating	Doing more walking	Joined gym/alternative exercise class	Exercise bike/rowing machine at home	Playing football		Not motivated at home	Lack of supervision at home	Not invited to hospital session	Waiting for start date	Too far to hospital	Lack of parking at hospital
P34	M	59	WB	H																X						X	X	X	X	X	X	X	X	X	X	X	Exercise class wasn't for him. Mornings not convenient as he is busy (househusband). Exercise bike and rowing machine at home on which he did more than in programme
P36	M	59	WB	H						X										X									X						Wife died 9 months after his PTCA. Attended morning session but taking too much time off work. Changed to evening session but overcrowded so very slow and needed to be home with dying wife. Does lots of walking		
P15	M	60	I	H																						X								Been given information about session times but is still waiting to hear from hospital. Misunderstanding about attendance. Would like to attend			
P5	M	62	WB	H							X										X														Too ill, has emphysema. Advised to stop. Does some walking		
P12	M	65	WB	H												X																			Too ill, breathless. Waiting for prostate surgery but poor health		
P22	M	66	WB	H																								X							Found exercises too easy. Not getting enough out of it. Couldn't be bothered to travel so far when he was doing more strenuous things at home - mainly decorating		
P14	M	67	P	H									X																	X					Times not suitable. He gets very bad indigestion so cannot exercise too soon after meals. Does some exercises at home every day. Would prefer home-based programme so he can do it at his convenience		

continued

TABLE 59 Patients' reasons for non-adherence to hospital-based cardiac rehabilitation programme^a (cont d)

Patient no.	M/F	Age (years)	Ethnicity ^b	Programme ^c	Personal				Health problems				Other activities				Programme-related reasons						Patients' reasons for non-adherence																													
					No need to do rehabilitation	Feeling well	In denial about heart disease	Never done any exercises before	Personal/family problems	Returned to work	Carer	Too ill	Angina	Arthritis	Spondylitis, back pain, spinal degeneration	Difficulty walking	Leg pain on walking	Emphysema	Breathless	Heart failure	Waiting for surgery/treatment	Receiving disability allowance		Told to stop	Housework	Gardening	Shopping	Decorating	Doing more walking	Joined gym/alternative exercise class	Exercise bike/rowing machine at home	Playing football	Not motivated at home	Lack of supervision at home	Not invited to hospital session	Waiting for start date	Too far to hospital	Lack of parking at hospital	Time not convenient	Didn't like hospital sessions	Other participants too old	Exercises too easy	Previous hospital CR experience									
P20	F	53	WB	H							×																	×																					Very bitter about heart attack. Went to ~6 sessions but everyone else was old and she didn't fit in. Doesn't feel well and struggling to do even limited housework			
P18	F	55	WB	H						×																																					Didn't want to do it at all. Told nurse at 1st session she still gets angina and was advised to wait before starting but will not go back. Heavy smoker. No changes to diet					
P38	F	63	I	H																																												Gets very breathless, stopped exercises when she developed angina. Can't walk far. Attended with husband (CABG) and would have continued. Hopes to do CR again after further treatment				
P27	F	64	WB	H																																													Very active. On 'exercise on prescription' does 1 h on crosstrainer at local gym 4 times a week, which she fits in around her cleaning jobs. Hospital-based programme too easy and inconvenient to get to			
P16	F	67	BC	H																																													Went to several sessions but her balloon angioplasty has failed and she was told to stop until it is redone. Walking difficulties due to back problems and bad knees			
P40	F	73	WB	H																																																When randomised she said she would not attend if allocated to hospital programme as it is too far to travel (2 buses). Now feeling better than she has done for years and doing lots of walking. Doesn't see the need for CR

^{a-c} See Table 58.

he walked and was playing golf twice per week so had followed some of the recommendations in the Heart Manual.

Knowledge and expectations of CR

Eight patients had previously attended CR (hospital-based programmes) following an earlier cardiac event and three other patients had close relatives (two husbands and one sister) who had attended CR and all were positive about participation.

“... my husband went there and I used to go with him, first few months. I know they do exercises and they take the blood pressure and everything. And my husband is very happy there. He goes twice a week. Still.”

(P38, female, 63 years, Indian, Hindu, hospital-based)

Other than these 11, none of the patients knew about CR prior to their invitation to attend and most said they had little idea of what to expect or how it might benefit them.

“I hadn’t thought about it, I didn’t really have any expectations at all, I just went along and did what I had to, but I didn’t expect anything.”

(P17, male, 47 years, hospital-based)

Other activity

The majority of the patients were continuing to exercise in some way, especially walking. Sixteen patients said that they had increased the amount of walking they did. Although it was not possible to assess the pace or distance objectively, this ranged from brisk regular walks of several miles to walking on the level around shops for a patient with emphysema. Patients also talked about housework, decorating and gardening as their exercise; they accepted that it was important to exercise and these activities fitted into their lifestyle. Patients also recognised that the exercise they were doing was not necessarily as vigorous as that recommended but felt that what they were doing was appropriate for them (*Box 1a*).

Alternative exercise programmes

Six patients had joined a gym or were taking part in an alternative exercise class. Patients P27, P44 and P49 reported how taking part in CR, even for a limited period, had given them the confidence to return to their previous daily activities and attend an exercise programme (*Box 1b*).

Other health problems

Twenty-two patients reported health problems which affected their ability to do an exercise programme and for 14 it was the key factor.

Patients aged over 70 years were less likely to report other health problems but it is probable that most older patients with other health problems declined to take part in the trial. More patients in the minority ethnic groups mentioned health problems compared with the White British group. The health of several patients had deteriorated since their entry into the trial and they were unable to exercise (*Box 1c*).

For many of these patients, their other health problems were a greater barrier to exercising than their heart condition, particularly emphysema, arthritis and back pain. Some of those on the hospital-based programme said they had been told to stop by the rehabilitation nurses. In some cases the patients were unable to manage even basic activities whereas for others it was specific exercises or walking which they found difficult but they remained active in other ways. Patients understood that it was important to exercise and tried to adapt the advice they were given to their individual circumstances. For example, patient P6 did not want to do the exercises but continued walking, and P5, who had emphysema, was unable to complete the exercise sessions at the hospital but was going out with his wife most days and walking at his own pace in an environment where he felt comfortable.

Home-based programme

Ten of the home patients said that lack of motivation was a factor and for eight it was the major factor; five of these patients changed to the hospital-based programme and three completed it successfully (*Box 2a, b*). Patients became bored with the exercises but, as intended by the programme, continued to increase their walking and appreciated the nurses’ home visits.

Use of the Heart Manual and relaxation tapes

Almost all of the patients thought the Heart Manual was good and many said they had learnt new things about their medication and diet and it had improved their understanding of how the heart works. Even patients who were not motivated to do the exercises found the Heart Manual helpful. A majority of patients said the tapes were good and many had used the relaxation tape regularly, especially early in their recovery, and several continued to use it (*Box 2c*).

Randomisation to hospital-based programme

Three patients who expressed a preference for the home-based programme were randomised to the hospital-based programme and were unwilling to attend any sessions, two because they were carers

BOX 1 Reasons for non-adherence or non-participation in CR**(a) Other activities**

"I work in the morning, I do what needs to be done in the morning and I have a rest in the afternoon. And then I get a meal at night, and I don't work after tea. I am afraid I don't exercise as much as I should, as you probably think I should. ... I wash every day, I iron every day, I cook every day, and that's about it. ... first thing in the morning isn't a good thing because I have to help [husband] to do a lot of things, and by night time I'm too tired. I'm too tired to do exercises. ... I suppose doing ordinary jobs is not the same, doing gardening is not the same, but I truthfully couldn't walk very far. I am not as steady on my feet as I ought to be, which is arthritis, but I don't sit down all day."

(P1, female, 79 years, carer, home-based programme)

"I do a lot of moving about. Like I said I've not taken to my chair all the time. And that thing [TV], we only come in about 4 o'clock and switch that on. But normally we just keep pottering about."

(P11, male, 77 years, hospital-based programme)

"... we've been too busy doing the decorating and the garden. I haven't had the chance to go out walking. But as I say I'm not still."

(P4, male, 72 years, home-based crossover)

(b) Alternative exercise programmes

"They were very nice down at [hospital], but it was just too far and I mean I was travelling and then I had to wait and all I was doing was just walking up and down and going on a bike with a thing on my wrist, which I was quite pleased at first because it was telling me that my heart was strong, ... so it did stop me worrying. But then afterwards I thought well I could go down the gym closer to home and sort of do more exercise ... It just wasn't enough for me.

... down the gym, this other lady I go with ... we can stop on the apparatus longer ... we do an hour. ... we were going four times [a week] but this other lady said she's getting a bit tired so we might drop one."

(P27, female, 65 years, hospital-based programme)

"When I first started to do them, I always used to do some in the morning and the afternoon like it said and I would have a particular time that I would do it, and the relaxation I would do it as well. But that gradually as, I got more, doing the things I normally do, I mean, this was when I was at home more, and I hadn't started to go out. Now, once I started walking to the shops, and gardening and things like that, then, I sort of, I was doing that anyway so I didn't bother so much about the exercises. ... I'd gone back to that [weekly 'exercise to music' class] fairly soon. I enjoy that."

(P44, female, 71 years, home-based programme)

(c) Other health problems

"I was still walking. Yes, I filled it in for 6 weeks I think, and I still carried on ...

When I first started doing the exercises I started getting a pain in my back. I haven't had pain like that for years ... I have had X-rays ... so when the nurse came I told her I did not want to do any more. I have not done them since."

(P6, male, 65 years, home-based programme)

"I did the first exercise, where you do 2 minutes and then you walk round the room, so I did that. ... When I got up to do the third one ... the nurse came and stopped me, told me to sit down and said forget about it because I was getting out of breath that quick. So I was going to do more damage with my breathing that I was going to gain by doing the exercises. So they just said do as much walking as you possibly can. So that's what we do. ... Most of the time we go walking round shops and I can walk round nice and steady and that, and there's something to occupy you while you're doing it. I seem to be able to walk a lot longer."

(P5, male, 62 years, hospital-based programme, emphysema)

"Done those, to start off with, until I found out I was bugged up after doing them so 'I ain't not doing this no more'. I didn't even feel I could go out and do any shopping or whatever. I thought, stuff that, I ain't doing that no more. So I didn't carry on with it. ... I did it for about 3 weeks."

(P46, male, 68 years, home-based programme, diabetes, kidney disease)

BOX 2 Home-based CR programme**(a) Motivation**

"I just couldn't get into it. ... But, when they stopped coming, I stopped doing it ... Call me lazy, if you like. ... I did for a bit, put it that way, and I felt all right, so I didn't bother after."

(P42, male, 76 years, home-based programme)

"Sometimes you think, 'Oh, do I have to bother? I'd rather go and sit and read a book'."

(P44, female, 71 years, home-based programme)

(b) Home-based to hospital-based crossover

"But on this home thing I was doing on my own and was bored. You know, it was boring, although I was doing certain ... going a bit further every day, you know, to it. I think, I can't really give it a fair trial because of me having, as I say, I've been going through a lot of stress. ... But it was boring on your own, it's terribly boring. I know it was to help me to get better and it was up to me to do these things."

(P7, female, 65 years, home-based crossover, completed hospital-based programme)

"Well I tried it [home-based CR] didn't I? And [CR nurse] came and saw me and I told her then ... there's just no motivation. There's no enjoyment in it, you go into the kitchen and what it says in the book and oh I go back and put the television on."

"... it's great [hospital-based CR]. You're with some of the other fellows and you're having a laugh and a joke ... and then before you know it you've done all your exercises ... you don't realise you're doing them and that's what I like about it."

(P4, male, 73 years, home-based crossover, previous hospital-based CR experience)

(c) Use of Heart Manual and relaxation tapes

"Yes, I filled all that in. ... I'm keeping that, there's a lot of information in there. If I get a bit worried or anything I can always refer to that."

(P6, male, 65 years, home-based programme)

"... but the information in the manual it was unbelievable. I've learned things from that that I've never known. Even though I'd had previous heart attacks."

(P45, male, 56 years, home-based programme)

"I tell you what I thought was good, and that is because I do know it was stress, and that was the stress tapes. And I used to listen to them all the time and decided that if things got where I got really panicky about them, which I have done, ... I have lain down and just listened to them, and I think I have slightly learnt them off the top of my head. So if I got stressed somewhere else I could sit down and do them. ... And I thought them tapes were brilliant."

(P3, female, 52 years, home-based programme)

and one because of the distance by bus, but all followed advice to increase their walking and had made changes to their diet (*Box 3a*).

Invitation to attend hospital-based programme

Three patients said they had not been invited to the hospital sessions and were still waiting to be called. It appeared there may have been a misunderstanding in some of these cases as the patients had been given the information about session times but did not think they had been given an appointment with a specific start date. This general issue was queried with the nurses who said that all non-attending patients were followed up by telephone and this was confirmed by some of the patients. These patients still

expressed a willingness to do the rehabilitation programme. Patient P21 had attended CR after a previous heart attack and had continued for many months as he enjoyed it so much (*Box 3b*).

Access

Access to the hospital programme was an issue for some patients travelling both by car or public transport. Heavy traffic, lack of parking and irregular bus services were among the difficulties raised. Patient P11 was offered an evening session but refused this although he was able to drive there himself. However, for another patient (P16), only the evening sessions were suitable because her daughters were at work during the day and she relied on them for transport (*Box 3c*).

BOX 3 Hospital-based CR programme**(a) Carer**

"I couldn't really be away too often, too long, so as I said I am doing my walking, which is pretty good exercise I believe, I know its not so strenuous as running, etc., but I didn't actually take part in the exercise routine. ... I've got no objection to doing it, but I think at my age as well, if there was a regular exercise I felt that would be good enough, something I hadn't done for years, i.e. walking."

(P8, male, 70 years, carer, hospital-based programme)

(b) Invitation to attend

"... but there is still nothing coming from hospital. ... Long time ago I been twice there [shuttle test] and they giving me paper for so many time, is timetable, but nothing coming from hospital. ... But last time gave me paper for timetable to evening, morning or afternoon what convenient time. ... I think .. we send you appointment, we let you know, but nothing coming."

(P15, male, 61 years, Indian, Muslim, hospital-based programme)

"I've had no letters, no contact, nothing. ... I had a couple of phone calls from them saying 'how are you getting on?', I say, 'yes, fine'. That was it basically."

(P37, male, 56 years, hospital-based programme)

(c) Access

"... they wanted me to go up to [hospital] of a night time and I said 'I'm sorry, I'm not being awkward, I don't go out of a night time'."

(P11, male, 77 years, hospital-based programme, drives own car)

"I missed quite a few sessions simply because I couldn't park. I would drive over there at 9 o'clock in the morning and the car park would be full, and after 10 trips around I'd just go home again. That was the major problem, the actual programme itself there was no problems and it was good."

(P17, male, 47 years, hospital-based programme)

(d) Age of participants

"... but they were all old. I went about six times and then I gave up because, as I say, they were all old people and they could all sit and relate to each other, but I mean there was nobody there my age. ... Because they were older I resented the fact that I was there. I felt as though I shouldn't be there. So I stopped going. ... they had had their life, I don't feel as though I've had mine."

(P20, female, 53 years, hospital-based programme)

(e) Experience of hospital programme

"... the first time I went down there I couldn't believe it. To me it was a shambles, it was an utter shambles. In my opinion there was too many people there. ... The second time I went down there, I stood it for the session and then I told them I wasn't going down there again. I just could not ... it just wasn't for me."

(P34, male, 60 years, hospital-based programme)

"I liked the friendship of the group, that's part of it I think, I'm a mixer I don't mind that at all. You can see if he's doing better than you and that's what you want isn't it?"

(P13, male, 58 years, hospital-based programme)

"Then there was more telling how the medicines ... This was quite good. I liked it. ... Yes, it was very, very helpful. Which medicine they give you, and what they do. And you can't take this medicine with that, its worse for you or harming you."

(P9, male, 56 years, Pakistani, hospital-based programme)

Age of participants

Three patients, aged between 52 and 60 years, on the hospital-based programme thought that the other patients attending the exercise session were "all old people" and did not feel comfortable with this (Box 3d).

Experience of hospital-based programme

Most patients enjoyed the atmosphere of the hospital programmes and found it friendly and fun. They enjoyed the company and gained motivation working in a group. Two patients thought it was overcrowded at one of the hospitals

and did not enjoy it. Patients who attended the education sessions found the information on medication particularly helpful (*Box 3e*).

Lifestyle changes

Following their cardiac event, all the patients were aware of the changes to their lifestyle that were recommended to improve their health and lower their risk of further heart disease, even if the motivation to make these changes was lacking (*Box 4*). Patients who had had a previous cardiac

event, or whose partner had health problems, had usually already made changes to their lifestyle. Many patients said they had made changes particularly around smoking and diet. The patient's partner or family often had an important role in supporting these changes which could also apply to others in the family. One Asian patient commented that when he discussed the changes in his diet with friends, they were all making the same changes and the message was being reinforced in the community.

BOX 4 Lifestyle changes

"I didn't know it was going to cause me that. So I just keep on eating. Now I know what fried things do for you. Now I don't have it any more now – I just stopped everything."

(P30, female, 50 years, Indian, Hindu, home-based programme)

"The wife helped me as best she could ... And she cut out cooking fats and all that, the greasy stuff ... She read it [Heart Manual] and she said, 'now you've got to stop with these fry ups in the morning, bacon, egg and sausage and all this'."

(P42, male, 75 years, home-based programme)

"They have changed the way he ... he used to have a lot more fried food before, and now they have cut it out and they are doing things like using olive oil which they've been told is better to cook in than vegetable oil or butter ..."

(Daughter P15)

"... but I know that I asking, when I sit there with the others, a few people like that, and I ask what you eat and this and that, the same one, everyone says 'we do like that', same thing."

(P15, male, 60 years, Indian, Muslim, hospital-based programme)

"We used to eat butter, but we stopped everything. ... Yes, everybody in the family using sunflower. And Flora for the margarine to spread on the bread."

(P9, male, 56 years, Pakistani, Muslim, hospital-based programme)

"I've got to admit that I haven't kept up to my diet sheet that's in the package there, the way I should do. I still eat a lot of salads, tuna, salmon and baked potatoes. But we do go out twice a week, Tuesdays and Saturdays, and have a decent meal. I don't have any fried stuff."

(P20, male, 69 years, carer, hospital-based programme)

"I am more active because now I know I have to do the exercise, before that if something is good on the telly I would prefer doing that rather than walking. But now I know I have to walk so I am taking that seriously."

(P35, male, 55 years, Indian, Hindu, home-based crossover)

"Well as I say I play golf [twice a week] and I do a lot of walking, I consider that exercise."

(P47, male, 70 years, home-based programme)

"I used to stop smoking. I could stop smoking for 5 years and then start again. ... the heart attack helped me to make up my mind and that was it so I haven't had a cigarette since. I did try to have a cigarette and it made me that bad and I thought forget it."

(P33, female, 61 years, home-based programme)

"I smoked and sat at a desk all day, and didn't do any exercise, ate whatever I wanted because I didn't put weight on, so it didn't bother me with what I was eating. So no, I was not a healthy person. ... [now] I watch what I eat, probably eat it anyway but at least I think about it. I do take more exercise and walk a lot. I still have the occasional cigarette, I must admit, but I have pretty well packed up."

(P17, male, 47 years, hospital-based programme)

Benefits of CR

Despite being unable or unwilling to exercise as much as expected, many patients were positive about CR. For example, patient P6 acknowledged how he had benefited from the home-based programme and patient P49 compared her experience with that of her husband who was not offered CR.

“If they had not got me out and if I sat in on my own at home I would be probably sitting there now. ... It pushed you outside, didn't it, to start getting about.”
(P6, male, 65 years, home-based)

“My husband's had a heart attack actually, at 40 he had one, but what his recovery was, mine was completely different and better because I had after care and my husband didn't. ... I hope to improve by me doing it really, not by itself. I mean I do watch now everything, I watch what I eat as I say, I go to keep fit now.”
(P49, female, 53 years, home-based)

Differences in reasons for non-adherence by age, gender and ethnic group

Only limited trends were found in reasons for non-adherence by age, gender or ethnic group.

The ethnic minority patients were more likely to cite health problems (cardiac and other physical problems) as reasons for not adhering to their CR programme. This was particularly focused in the white Irish group who were younger (mean age 56.8 years) than the other groups (mean age 63.7 years), yet four out of five cited health problems. Fewer patients in the ethnic minority groups mentioned personal difficulties that prevented CR participation (such as being a carer, returning to work, feeling well or that they did not need to do CR) than the white British patients.

On the home-based programme, motivation to do the daily exercise component of the Heart Manual appeared to be a predominant factor for non-

adherence in the women, with seven out of the 10 women interviewed citing this compared with only three out of 11 men.

Whereas only one woman felt too unwell to participate in the rehabilitation, five men described this as a problem that prevented their participation.

More women cited domestic tasks such as housework, shopping, gardening and decoration (5/10) as reasons for non-adherence compared with men (5/33). Overall, the women cited more reasons than the men (61 reasons for the 16 women and 96 for the 33 men) for non-adherence.

The only difference identified between younger and older participants (aged 70 years or more) was that older patients were less likely to cite health reasons than younger patients.

Focus groups of adherers

Participants

Sixteen patients from the hospital-based programmes participated in three focus groups and 10 patients from the home-based programmes participated in two focus groups (*Table 60*).

Patients in the hospital-based programme

Each hospital organised their CR programme differently depending on the staff and facilities available. The three groups of hospital-based patients expressed very similar views about CR and all spoke very favourably about the benefit of attending the programme.

Experience of hospital-based exercise sessions

Patients enjoyed exercising in a group and mixing with other people was a positive experience for all

TABLE 60 Characteristics of focus group participants

	Agreed to participate	Attended	Males (n)	Mean age ^a (years)	Age range
Centre-based					
Hospital 1	8	6	4	62	45–75
Hospital 2	8	5	4	65	59–75
Hospitals 3 and 4	6	5	4	62	57–69
Home-based					
Hospitals 1 and 2	5	4	2	63	59–67
Hospitals 3 and 4	6	6	5	62	50–75

^a Patients' age at time of randomisation into BRUM trial.

the patients. They described this as like belonging to one community and being related to each other. Patients gained both motivation and support from other patients.

“I don’t think it’s so much the exercises, it’s the camaraderie that you get.”

(M, Hospitals 3 and 4)

The programme at each hospital varied slightly and used different exercises and had different equipment available.

“I thought it was a good balance between the walking and the lifting and the tread up and down. I thought there was a good balance once you went on the rotation. They give you a little bit of everything there.”

(M, Hospital 2)

Patients at Hospital 1 thought that the exercise sessions were sometimes overcrowded and they sometimes had to wait to use an exercise bike, but acknowledged this was due to the success of the programme. Patients also had to wait to have their blood pressure checked before they could start exercising. Despite this, they thought that the programme was well equipped and enjoyed using the different equipment.

“There’s quite a bit of equipment over there but it’s certainly packed, isn’t it?”

(M, Hospital 1)

“And its also comforting to have your blood pressure taken.”

(M, Hospital 1)

Patients at Hospitals 3 and 4 were taught to record their pulse rate before and after exercise, which they found helpful. However, the order in which they did the exercises could affect their final pulse rate so they would sometimes manipulate the starting point in order to end on an exercise which would suit them.

“I didn’t particularly like the way they were set. You’ve sort of got four easy ones next to each other, and then you get three or four really hard ones. If you’re finished on them, you pulse is going like three times faster and they say, ‘Oh you’re doing too much ...’”

(M, Hospitals 3 and 4)

“I cheated a couple of times, because I wasn’t working out hard enough and so I found the one machine that really got your pulse going [to finish on] and I made sure that I clocked it.”

(F, Hospitals 3 and 4)

The patients attending Hospital 2 reported that the exercises were not too strenuous and two

patients found them easy as they were used to physical activity, although they also acknowledged that not everyone found it easy.

“I thought it would be harder, I thought they’d be pushing us. I thought they’d be trying to see how far they could push us.”

(M, Hospital 2)

“I was with a few who were, probably a little bit more overweight, and I think they were struggling.”

(M, Hospital 2)

Patients described a sense of achievement and increasing confidence as they progressed through the exercise programme.

“I think it’s self-satisfaction that you’ve actually done it as well. You feel a bit chuffed with yourself, you think, especially after you’ve been a couple of times, ... you’re doing that particular exercise on one machine ... ‘Oh, I’ve done that a bit better; I haven’t found that such a struggle.’ And it makes you feel better, and that’s when your confidence starts coming back.”

(F, Hospitals 3 and 4)

One patient found the exercises awkward because of arthritis and a hip replacement and another patient had a back problem and found the rowing machine difficult so did not use it, but otherwise patients reported few problems with the exercises.

Experience of hospital-based education sessions

At Hospitals 2, 3 and 4 the education sessions were combined with the exercise sessions and at Hospital 1 the exercise and education sessions were held on separate days. Views on the education sessions were more mixed and the quality of the talks was variable. The education sessions also appeared to be less well organised as the speakers did not always arrive as expected or talks were repeated and patients were given the same talk at more than one session. Comments included “some were boring, some were good”, “every week you learn something”, “a couple of times I was there and nobody came”, “too much talking”, “very informative”, “very helpful” and “I enjoyed the talks”. However, in general patients thought the education programme helped them learn more about what had happened to them and how to improve their lifestyle. Patients had also received useful written information and one patient had seen an information video. For the majority of patients, motivation to exercise was felt to be a problem and they needed the support of others around them. This was seen as one of the main benefits of attending the hospital programme.

“I enjoyed the talking. I think, what they told us about the tablets and what they were and all that ... The best advice was the diet.”

(F, Hospital 2)

“But I did come to rely on coming to these meetings and seeing people and understanding what was going on.”

(M, Hospitals 3 and 4)

The sessions on medication were particularly valued and sometimes over-ran as patients asked so many questions. Patients found the advice helpful and reassuring.

“If you miss one [tablet], she said it doesn't really matter that much because it sort of goes up and down slowly. So that was comforting. And the spray, she said you can use that as much as you like, you couldn't sort of overdose on it.”

(M, Hospital 1)

There were mixed views about the relaxation sessions. A few patients had been given relaxation tapes to use at home. At Hospital 1 the relaxation sessions were run separately from the exercise sessions and several patients had not attended any and did not know about them.

“I didn't think any [sessions] were [boring] ... I enjoyed all of them, even the relaxation one. I enjoyed that. Well, I still keep putting the tape on now and dropping off on the bed.”

(M, Hospital 2)

“I didn't enjoy the relaxation ... I don't like lying on the floor and listening to silly music.”

(F, Hospital 3)

Patients all said they had followed advice given in the talks such as eating more fruit and vegetables. However, they also pointed out that they were already aware of some of the advice about healthy eating and smoking before their cardiac event but most did not think it applied to them.

“Completely [changed diet]. I don't eat any more oily stuff now. Like samosa or pakoras, anything cooked in the butter that I used to eat. I stopping all those now and start eat vegetable, boiled vegetable.”

(M, Hospital 1)

“You'd watch a programme on television about healthy eating and all this and all that, and I'd look at myself and – ‘I don't need that!’”

(M, Hospital 2)

“I used to smoke a lot when I was younger. And I would watch a programme on lung cancer with a cigarette in my hand.”

(M, Hospital 2)

For many it had taken the shock of having a heart attack or surgery before they made lifestyle changes. The education sessions had provided the support to make the changes. One patient explained how difficult it was to make others understand the need to make changes earlier in their lives.

“Well my son's got to be about 16, 17 stone. He is massive. He sits there all day long with a box of Maltesers ... and I'm on to him all the time. ‘Martin, you'll finish up like me’. ‘Oh no, no, I won't, I won't.’ You can't educate them. He just won't listen.”

(F, Hospital 2)

There was a feeling that people needed educating about looking after their health even before they experience symptoms of heart disease, and patients described personal experiences of being treated for indigestion or having very high blood pressure of which they were unaware prior to their cardiac event.

Patients said they took a more relaxed approach to everyday life and getting things done. One used the example of home decorating and doing ‘one wall a day’ rather than completing a whole room in a weekend.

“I've learned to say ‘no’ to a lot of things since I've been on this course and listened to the talks.”

(M, Hospital 3)

The only suggestion for improving the programme was to include a smoking cessation programme for those who needed it.

Access to hospital-based programmes

None of the focus group patients had problems getting to the hospital for CR. Most travelled by bus and none required family or friends to take them to the hospital by car. Patients at Hospital 1 complained about the difficulty with parking.

“... the car parking was a very serious problem. ... But I come on a bicycle now [continuation programme] ... It would be lunatic to try and come by bus from where I live. It's two miles in a straight line and it would take me an hour on the bus.”

(M, Hospital 1)

Patients were satisfied with the time of the session they were offered and none described problems with session times. One patient was working and had been able to negotiate time off to attend.

“I was working. I was taking invalid kids and that to school on the buses, but I worked it so that, the afternoon shift, I just skipped it, like. ... I'd get someone to cover me. ... I worked it out with the gaffer.”

(M, Hospital 2)

Benefits of cardiac rehabilitation

Patients said they enjoyed the programmes and gave factors such as having a chat, meeting other people, feeling more at ease with people who had the same problem as themselves, having someone to ask about problems and having someone keep a check on them as reasons why they enjoyed attending. At the hospital they enjoyed talking to other patients and sharing their experiences and valued staff supervision as without it they thought they would be scared to push themselves as far.

“... after I had my heart attack my idea was that’s the end of my life. But going on this programme, it’s sort of to talking to other people and the people who run it, I realised there’s things you can do. I practically do what I used to apart from working like I used to.”

(M, Hospital 3)

Patients were very positive about CR. In addition to the immediate benefit of enjoying the sessions, patients felt there were longer term benefits in their mood and confidence. It would have been easy to sit and do nothing at home and ‘turn into a cabbage’. CR enabled them to carry on with a normal life and return to doing things they enjoyed. All the patients would recommend CR to everyone who has had a heart attack or heart surgery.

“I found I was a lot better mentally when I was coming on this rehabilitation programme.”

(F, Hospital 3)

“If you can do the exercises here, then there’s lots of things you can do, which you’d be frightened to do at home.”

(M, Hospital 1)

Patients had also learnt to cope with sudden pains and not assume they were experiencing a heart attack every time.

“Well, without somebody to help you, if you got a sudden bit of a sharp pain in your chest or something you think ‘oh sod that, its another heart attack’, but it’s not one.”

(M, Hospital 3)

Maintenance programmes and other exercise

At Hospital 2 there was a continuation programme available at two other venues in the community. Only one of the patients was still attending this, although all were taking part in some form of activity and one had bought an exercise bike to use at home.

“Well I go swimming now three times a week. At least an hour a session. And I find that helps. ... and that’s

why I’ve gone back to swimming, which I found I could extend myself more swimming than I could actually walking, which is better for me.”

(M, Hospital 2, arthritis)

Similarly, the patients from Hospitals 3 and 4 were all continuing to exercise in some way, for example, going to a gym with friends and walking. At Hospitals 3 and 4 there was no continuation programme and this provoked mixed views as to whether the hospital should provide this, particularly as facilities were limited and were sometimes overcrowded, or whether patients should exercise independently. They supported the idea of a maintenance programme in the community as that would give them the motivation to exercise regularly.

“I was lost I was in the few weeks after it stopped. I’d got so used to coming in certain days, it was in my routine, and I really missed it. ... we ought to be the given the choice whether we’d like to continue or, even if we only came once a month, or even in 6 months time, do like a month’s session or something. I think it should be a continual thing.”

(F, Hospital 3)

At Hospital 1 there was a continuation programme available both at the hospital and at another venue. Five of the six focus group participants were attending a continuation programme, four of them at the hospital. The sixth patient had had surgery for a slipped disc since attending CR but had recovered and expressed interest in attending a continuation programme. Patients commented that the sessions at the hospital were very busy and there was often a wait to use equipment so they were having to stagger the times at which they arrived. They suggested that the programme at Hospital 1 was a victim of its own success and was reaching the point at which access would have to be restricted for patients who had already completed the initial programme. Patients attending a continuation programme at the hospital appeared reluctant to exercise independently outside this environment.

“I think part of the ... no, not problem, but I mean part of the situation that you’ve described, is that many people, like me, continue to come after the first 12 weeks, on the maintenance programme. Now, the reason I do it is quite simple: it’s very good. To go anywhere else might not be so good, and I’d have to find somewhere else to go. It’s probably much cheaper than going to a private gym.”

(M, Hospital 1)

In order for patients to exercise long term they felt they needed to do a form of exercise which

they enjoy, which fits in with their lifestyle or has a purpose, as exercise for its own sake was unlikely to motivate them.

“... if I’m going on my walk, I like to ... even if it’s only going to get ... to ASDA ... I like an objective. Like when we do our rambles there’s always, apart from the scenery, there’s always something there. Enjoy it.”

(M, Hospital 2)

Making exercise a social occasion was also useful in motivating patients to exercise independently.

“I’m a very lazy person in the sense that I need people around me to push me to do exercises, and I find it better when there’s a crowd of you, you know. Now if my two exercise partners don’t want to go to the gym where I live now, I don’t go. And I get annoyed with myself then ...”

(F, Hospital 3)

Patients in the home programme Experience of the Heart Manual

Patients spoke very highly of the Heart Manual: it was generally well organised, covered a range of topics in addition to exercise, provided helpful information and advice and was very positive and encouraging. The advice was also relevant to the patients’ experience. Several patients thought they would not have received this level of information and advice from the hospital programme, suggesting a limited understanding of the hospital programme.

“I felt it was so well put together and so very sensibly laid out because it didn’t just deal with the exercise, it dealt with the emotional side and the dietary side and the psychological effect of it and I thought ‘yes, that’s for me’, because I don’t think I could have got that from a hospital.”

(M, Hospital 3)

Some patients suggested that the information and advice given to them in hospital at the time of their cardiac event was difficult to take in, especially if they were in denial over a heart attack, but being able to read the Heart Manual in their own time enabled them to understand their condition better. The Heart Manual enabled patients to take positive steps to help themselves. Patients continued to refer to the Heart Manual occasionally as a source of information long after completing the programme.

“You have people start talking to you, like doctors and saying do this, do that and do that ... But you know, with the book you keep reading it every day.”

(F, Hospital 1)

The information on medication was also considered to be very good as it described the effect of the different drugs used for patients with heart disease. Patients reported reading and following the dietary advice in the Heart Manual, although sometimes a patient’s wife would take the lead in making dietary changes. Patients reported cutting out some foods, reducing salt, fat and sugar and checking food labels when shopping. One patient had decided not to follow such a strict diet as she thought that at her age enjoying life was as important.

“I think my diet’s worse now than before I had the heart attack. I was very careful with whatever I ate and drank, still had a heart attack. You know at my age, why am I bothering? My three score years and ten have gone and I think well I’ll enjoy a little bit more. All those years I didn’t have a pudding ... No chocolate and no biscuits and it didn’t make any difference. ... Would I have had it earlier? I don’t know.”

(F, Hospital 1)

Although praise for the Heart Manual was unanimous, one patient with arthritis who found walking difficult suggested that patients should not be made to feel that everyone should be able to do everything recommended in the Heart Manual. Another patient had been using the Heart Manual for several weeks before he realised there was a description of the exercises on the inside back cover and thought it would be helpful to have a pointer to this early in the Manual. Patients generally felt that the Heart Manual answered most of their questions.

“The only thing I found, to start with when I was working through week by week, I didn’t pick up the exercises right at the back, till a couple of weeks, and then I spun through and I saw them, but there wasn’t anything that was said, ‘refer to the back of the book for your exercises’.”

(M, Hospital 3)

“I think a little bit more reassurance on one or two things, in the early days. I was concerned about angina. And sometimes I did feel quite rotten and I wanted to know whether I should be using my GTN spray or whether if I used it too often it would be less effective and all that sort of thing, and that kind of area possibly a little bit more help on ...”

(M, Hospital 1)

Relaxation tapes

Overall, the relaxation tapes were considered to be good and all except one patient said they had used them, although one patient had found it difficult to get used to using them but had

persevered with the part he found most beneficial. The patient who did not use the tapes said he preferred to listen to a CD of quiet music and “just shut my ears to everything going on round me”. Patients thought they had learnt to relax through listening to the tapes and were able to apply the techniques in stressful situations. Although patients had found the tapes helpful at the time, they were only using the tapes occasionally or not at all since completing the programme.

“And I found that listening to the tapes and I knew how to get myself calm and I could sit, on the time that they were sort of saying well we’ll take your blood pressure now, and I could do these, this calm thing and it’s [‘white coat syndrome’] been absolutely fabulous since then. ... if you have a day when you really feel like sort of scraping somebody off the ceiling, if you listen to them then it just ... brings you down again.”

(F, Hospital 3)

Experience of home-based exercises

Patients thought the exercises were well planned and the gradual build-up helped to build confidence as initially patients found exercising difficult.

“It was a matter of getting confidence about how much you could do, ‘cause you were told to take things very easy for the first like fortnight, or month even, and I did do that. But I found that to start with the walking, even sort of just walking round the block, was quite a strain.”

(M, Hospital 1)

A few patients said they were worried about exercising on their own, especially early on in the programme, and were reluctant to push themselves. One patient got his wife to do them with him as he did not like to exercise on his own.

“I’ve got to be honest, I didn’t do as many as I told her I was doing in the first couple of weeks. I was a little bit like you, I was a little bit worried if you know what I mean.”

(M, Hospital 1)

Recording the exercises patients had completed could help with motivation as patients knew the nurse would be coming and would check up on them. Patients also found it encouraging to look back and see the progress they had made over the weeks.

“It also gave you a kind of target, remember to do the exercises twice a day, ... and also the fact that you were encouraged to do a walk every day. Not that I did ‘cause sometimes it rained or it snowed or some

reason, you know. But it gave you a target because you had to fill it in, and you were thinking your cardiac nurse will be back and sort of look through that and say ‘why didn’t you do that?’ so you kept it up, and I think that’s good.”

(M, Hospital 1)

None of the patients in the home-based group had other health problems severe enough to restrict exercising significantly and were able to work around them, although one patient had arthritis in both hips and found walking difficult. Two other patients had specific problems and, after discussion with the nurse, stopped the exercise which aggravated their problem and did more of the other exercises. Another patient in the home-based programme found the exercise which involved bending too difficult as he was overweight at the time so he stopped doing it. Patients were able to work around their other problems.

“I had trouble with the knee bending one. ... I discussed it with [nurse] first and she said, well, cut that one out and do some others instead. Not others, you know, increase what was in there.”

(M, Hospital 3)

“I suffer with both tendons in both upper arms so that was no good to me, that one, so I told [nurse] and she said just increase the other ones.”

(M, Hospital 3)

Many patients had received support from family members who also did the exercises with them.

“[Husband] said ‘no, I don’t think it’s easy, but you look ever so funny doing it.’ ... so that’s when he started doing it and it was a help. ... He don’t do the night one though. But he used to do the early morning one. He still has a go. He says ‘it makes you feel good don’t it?’”

(F, Hospital 1)

“It was difficult in my case because my wife had a stroke ... she’s a wheelchair user and is partially paralysed ... so she couldn’t do the exercises with me ... but she was very amused when I did them. And she also reminded me to do them.”

(M, Hospital 1)

Experience of nurse support

Patients were positive about the support they received from the nurses and thought that the number of visits was about right, although one 75-year-old widow felt that, because of her circumstances, she would have liked more home visits in the first 6 months. Patients described the nurses as very friendly, easy to talk to, helpful and knowledgeable. Only one patient reported

telephoning the nurse for advice in addition to the routine calls.

“I found that when they came in that you could talk to them on a one to one basis. I mean my medication was changed within the first week. ... And she done it on the afternoon, she phoned me back, said she’s arranged all that. ‘Go to your GP to pick the prescription up’ sort of thing. That was all done in one day. I don’t think you’d have done that if you’d gone to the hospital.”

(M, Hospital 1)

“And there was always the opportunity to ring which I did on one occasion. I was a bit concerned at one time because I thought the angina was not as under control as I would like. ... but it was helpful to be able to do that.”

(M, Hospital 1)

Benefits of cardiac rehabilitation

As with the hospital-based programme patients, the home-based patients found that CR helped them to regain confidence after their cardiac event. Several said they were learning to overcome the panic they experienced when they were breathless or felt any pains.

“I found coming up here today up that slope ... up from the car park ... by the time I got to the top I was puffing a bit. But I don’t panic any more you see. I would have stood there thinking ‘ohhh, this is it.’”

(F, Hospital 3)

“It’s always the stress that brings it, and the breathing goes funny and you realise that you’ve just been worrying about something and when you stop worrying, which is what our exercises and relaxation were telling us to do, you stop worrying, you can feel it all drain back. You can breathe again properly and think better. And that’s what it really taught you to do I think.”

(F, Hospital 1)

Patients said they had also learnt a lot about the causes of heart disease and healthier lifestyles and this had helped them regain confidence and control. This enabled them to return to a more active lifestyle and also to know when not to take on more than they wanted.

“I thought I always ate healthily and I stopped smoking 8 years ago when my brother died of heart attack, and I thought I walked a lot and done good exercise but when I went through that book I couldn’t believe what I was doing wrong, I was eating everything wrong, no wonder I’d got really high cholesterol ... I weren’t taking the exercise what I thought I was. And it really helped me, well I still do all the exercises.”

(F, Hospital 1)

Continuing to exercise

Only a few patients reported continuing regularly with the exercises in the Heart Manual after finishing the programme, although most said they were doing more walking. Patients showed that they understood the importance of continuing to exercise regularly. One patient had bought a dog to help with motivation as he felt he had a duty to walk it twice a day and another had bought an exercise bike. Patients felt that on some days they were able to do more than others and some still had concerns about doing too much. Bad weather could restrict the amount of walking patients were able to do.

“... I still do the exercise programme actually, because I think it’s great. Keeps me fit. ... but it’s exercise, because I do like to walk a lot, but in the bad weather it’s freezing cold and wet, you don’t really want to go out and do it. ... So you do it at home, I think it’s great, personally.”

(M, Hospitals 3 and 4)

“Not the ones in the book, but I go swimming now whereas I didn’t used to before, and as I say I walk a hell of a lot now. You know, whereas I’d got to go somewhere I’d jump in the car, now I walk and use the bus, really.”

(M, Hospitals 3 and 4)

Several patients had included activities which involved group exercise, such as keep-fit classes, as part of their ongoing exercise programme. One patient was attending a weekly Heart-Throbs group backed by the British Heart Foundation at a leisure centre which included exercise and relaxation.

“I don’t work Wednesdays and I’m part of [place name] Health Walks ... they do a whole day on Wednesday ... I mean I can easily walk ten miles now, no problem. When you’re with a group you don’t really notice it you see.”

(F, Hospital 1)

A few patients suggested that as their recovery progressed it became more difficult to find the time to exercise as they had other commitments.

“You have to restrict your own pleasure in walking and whatever ’cause somebody else has got demands on your time. In those first few weeks everybody’s quite prepared to let you have all the time you need but then as you get better and better they encroach on that time.”

(F, Hospital 1)

A patient with arthritis described the difficulty of maintaining the recommended exercise levels.

“I have a bit of arthritis in my hips so I mean I do try and do the exercises but the actual walking, I find it a

great effort and when I read in the book, you know, you should be walking X number of miles in the next six months, there's no way I can do that. ... so I don't quite know what you replace it with. I mean the exercises, OK I can do as many of those as I can do and that's a bit ... it gets a bit boring after a time. I do play bowls in the summer, so that keeps me fairly fit but the winter's a bit dire "

(F, Hospitals 3 and 4)

Interviews with Punjabi-speaking participants

Ten Punjabi-speaking participants were interviewed; five were allocated to the centre-based programme and five to the home-based programme, one of whom was invited in error to the hospital-based programme and therefore crossed over to the hospital-based programme; three were female. The three women spoke little or no English, three of the men spoke only a little English and seven read no English.

The majority had made changes to their lifestyle following their cardiac event, mainly reducing the fat content of their diet and increased walking.

I can walk and feel fine ... I go walk everyday. I can walk up to 15–20 minutes.

(F, home-based crossover to Hospital 1)

The home-based participants described listening to the Punjabi Heart Manual tape. They all were in favour of the home-based programme because of the convenience of the location, although one man who had had a bypass operation felt that the exercise regime was not strenuous enough for him as he felt fairly fit after his operation. One man described how he gained a greater knowledge of diet and exercise from the Punjabi Heart Manual tape.

The participant who crossed over from the home- to the hospital-based programme found the motivation to exercise alone hard and was encouraged to do more exercise by watching other people exercising in the hospital-based programme and felt safer exercising in a hospital situation.

Like sometimes I think to do that exercise tomorrow ... or day after tomorrow, cannot do every day. ... I will prefer hospital. ... If I get some problem they (hospital) can see me.

(F, home-based crossover to Hospital 1)

Chapter 5

Discussion

Health outcomes

This study is the largest trial of home-based compared with centre-based CR to date and has a longer duration of follow-up than other reported trials. The study has shown that for people of low to moderate risk after an MI or revascularisation (PTCA or CABG), home-based CR using the Heart Manual resulted in outcomes that were not statistically significantly different from those patients offered centre-based rehabilitation. However, the width of the CIs around the mean differences indicates that we are unable fully to exclude clinically significant differences, particularly for SBP and DBP. A significantly higher proportion (96.1%) of patients randomised to receive the home-based programme received five or more contacts with a rehabilitation nurse than patients in the hospital-based arm (56.1%), but this did not translate into lower levels of cardiac risk factors than in those who were offered the centre-based programme.

The outcomes between the groups did not vary in an interactions analysis for any of the prespecified subgroups (gender, age, ethnicity, initial diagnosis or centre). Comparisons between home- and each centre-based programme, undertaken as a *post hoc* analysis found the largest difference between home- and centre-based CR for Hospital 1 at 6-month follow-up, which fits with its greatest 'dose' of supervised exercise. However, by 1 year of follow-up the largest difference (in favour of the centre-based programme) was for the programme with the lowest intensity of supervised exercise (Hospital 2). Our prior hypothesis that those groups who were reported to have a poor uptake of CR might gain greater benefits from the home-based programme, whereas those with high levels of hospital attendance might do better in the centre-based programme, was not supported. A recent non-randomised study explored the issue of patient preference and location of CR and found that Caucasian, working, time-constrained individuals preferred a home-based programme, whereas non-working and ethnic minority patients preferred a centre-based programme.⁸⁴

We also hypothesised that participants of the home-based programme might sustain the improvements

achieved in exercise capacity after the end of the programme better than those in the centre-based group as they would have the opportunity to build their physical activity regime into their lifestyle from the start of their CR. We did not have a measure of exercise capacity at baseline, but found that the distance walked on the ISWT declined equally in both groups from the 6-month to the 2-year follow-up. This is in contrast to sustained changes over 2 years reported after a residential rehabilitation programme in Switzerland.¹³⁵

Over the 2 years there were only a small number of cardiac events equally distributed between the home- and centre-based arms. There was a suggestion, although not statistically significant, that there may have been more deaths and MIs in the home-based group. This is probably due to chance as there are no differences in clinical measures, such as prescribing of secondary preventive medications, or cardiac risk factors to explain such a difference.

Comparison with the results of previous trials

There have been seven previous RCTs comparing home-based with centre-based CR.^{28-31,34,82,95,97,136} Two of these trials took place in the UK and used the Heart Manual,^{34,82} but the BRUM trial is of significance because of its size and the populations in which it took place, largely in inner-city, multi-ethnic, socio-economically deprived communities. In addition, this study included patients post-revascularisation and developed a new version of the Heart Manual for these patients. Both of the previous trials found results similar to ours with no difference in cardiac outcomes between patients randomised to the home- and hospital-based programmes. Bell reported similar improvements in functional capacity in the patients randomised to the home- and hospital-based arms, with no statistical difference between these groups.³⁴ Dalal and colleagues reported a significantly greater improvement in exercise capacity in patients in the home-based rehabilitation arm from 3 to 9 months of follow-up compared with the hospital-based group.⁸² In this trial there were similar and significant improvements in the HADS depression score, Quality of Life after Myocardial Infarction score and TC in both groups.

In another trial comparing home- with centre-based CR, which took place in Italy, the participants in the home-based arm received four to eight centre-based rehabilitation sessions prior to the home element, in addition to a monthly support group, which is similar in intensity to the hospital with the lowest number of sessions in our trial. In addition, the patients in the home-based arm were loaned a cycle ergometer for 2 months and received visits fortnightly from an exercise specialist. The hospital-based programme was both longer and more intensive than specified by the NSF for Coronary Heart Disease, with 40 supervised exercise sessions and twice weekly risk factor management counselling.⁹⁵ This study found significant improvements in exercise capacity from baseline to follow-up in the home- and centre-based groups, but no significant differences between the groups at follow-up. Similarly, health status measured using the Sickness Impact Profile improved in participants below the age of 75 years in both home- and centre-based groups, with no difference between these groups at follow-up.

A study of post-CABG patients in Canada found a similar improvement in exercise capacity in patients in the home and hospital arms. In addition, patients in the home-based group reported greater improvements in the PCS of the SF-36 than the hospital-based arm.¹³⁶ The hospital-based programme was longer and of greater intensity than usually provided in the UK, with supervised exercise sessions three times each week for a 6-month period. The home-based programme was more intensive than that of the Heart Manual, with two hour-long visits at baseline and 3 months and fortnightly telephone support up to 6 months.

Two of the trials used a home-based programme which involved three-times weekly cycle ergometry in which their ECG was monitored transtelephonically.²⁸⁻³¹ Both reported similar improvements in exercise capacity in the home- and hospital-based groups, but this intervention requires a high level of supervision and monitoring.

Carlson and colleagues compared a hospital-based programme with a modified programme which weaned participants from the hospital-based programme to do their exercise at home.⁹⁷ Both groups achieved similar improvements in exercise capacity and in serum cholesterol level at follow-up. However, due to the design, the participants in the modified group and the hospital-based group

actually attended a similar number of supervised exercise sessions on the hospital site.

The BRUM study was unusual in the length of follow-up, 2 years. Of the other trials comparing home- with centre-based CR, the longest follow-up was for 14 months.⁹⁵ In both groups the early changes in smoking cessation were sustained over the follow-up and improvements continued to occur to anxiety levels and HDL-cholesterol. The early rise in blood pressure seen at the 6-month follow-up fell over the later follow-up periods, but did not reach the baseline levels. Exercise capacity, measured using the ISWT, fell both from 6 to 12 and from 12 to 24 months, in contrast to the sustained change seen in some programmes.^{34,95}

We found no improvement in depression scores (as measured by the HADS). CR has a poor record in reducing levels of depression in participants. Several trials have reported a fall in depression score over a 1-year period in home- and centre-based CR trials, but although the depression scores reduced over time, this was not significantly different between the intervention and control groups.¹³⁷⁻¹³⁹ One of these was a large RCT of 1376 patients of a psychosocial intervention targeted at post-MI patients with psychological morbidity and found only a small impact on depression, with no statistically significant benefit over the patients in the control group.¹³⁸ A previous trial using the Heart Manual reported a significant reduction in the numbers of cases of depression at the follow-up points of 6 weeks, 6 months and 1 year, but no difference in HADS depression score after 6 weeks between the intervention and control groups.³⁵ The other evaluation using the Heart Manual failed to find either significant differences in depression scores between Heart Manual and either control or centre-based groups, or significant changes in depression score over time in any group.³⁴

We found a rise of 10 mmHg in blood pressure from the baseline to the 6-month assessment. This may be partially due to an artificially low blood pressure immediately following MI, but also occurred (although to a lesser degree) in the patients who had a revascularisation procedure. A possible explanation is the reduction in dose of anti-anginal medications after a successful revascularisation, as these also have an effect on blood pressure. Other studies have also reported a rise in blood pressure in a post-CABG population,^{140,141} post-MI and angina¹¹⁵ and for patients with coronary artery disease.¹⁴²

Adherence

A strength of this study compared with the two previous trials using the Heart Manual^{34,82} is that we used the same measure of adherence for participants in both home- and centre-based arms. It is difficult to make a comparable measure of adherence to a home-based programme as adherence to a centre-based programme is usually defined by the number of sessions attended.

Accepting a visit from a rehabilitation nurse at home requires less commitment from the patient and gives no measure of the amount of physical activity undertaken. Without the use of costly accelerometers or cycle ergometers, it is not possible to measure frequency and intensity of home-based physical activity objectively. We relied on patient self-report, and found that participants in the home-based programme reported more physical activity, significantly so among the ethnic minority participants and at an early phase among elderly participants. Two other trials have found more self-reported physical activity in the patients assigned to a home-based programme.^{97,136}

Carlson and colleagues reported a greater amount of exercise undertaken by participants in the home-based programme compared with those who undertook all their exercise rehabilitation in a supervised centre-based setting, but this differs from our study in that both groups started with a hospital-based programme, from which those receiving the modified protocol were weaned to undertake the exercise unsupervised at home.⁹⁷

Arthur and colleagues used patient logs to measure duration and frequency of physical activity and patients in the home-based group reported a mean of 6.5 exercise sessions each week compared with 3.7 sessions in the hospital-based group.¹³⁶

Internal validity

The BRUM study was randomised, which acts to reduce the potential for confounding and selection bias. The large number of patients recruited to the trial resulted in very similar baseline characteristics for each group, which is a strength of the study. We reduced the likelihood of allocation bias by using an independent group for the randomisation. Both groups were offered an active intervention, so we should have overcome the potential for the Hawthorne effect seen in trials where half of the participants are in a control group. In a trial of CR it is obviously impossible to blind patients and their healthcare staff as to which intervention they receive, but we tried to keep the outcome

assessment blinded by the follow-up assessments being undertaken by a nurse who had not recruited or provided treatment to the patient.

As the study had very low rates of loss to follow-up and with equal loss in each arm, it is unlikely that we had attrition bias between the groups due to loss to follow-up. At the 2-year follow-up we were able to account for the status (alive/deceased) of 98% of all the patients who entered the trial.

A potential weakness of this trial is the absence of a no-rehabilitation control arm. Although we have reported similar improvements in cardiac risk factors in patients allocated to both the home- and centre-based programmes, we cannot prove incontrovertibly that these changes would not have occurred as part of the normal recovery process. However, at the design phase of the study we felt that there was sufficient evidence for the benefits of CR to prevent us from having a control arm. Several systematic reviews have reported significant reductions in mortality in patients randomised to exercise-only or comprehensive CR programmes.^{12,13} Three trials have compared hospital-based, home-based and no CR^{28,29,31,34,95} and all have reported greater improvements in the patients in the groups receiving rehabilitation. Bell reported a significantly greater improvement in symptom-limited exercise at both 20 weeks and 1 year in patients randomised to receive the Heart Manual when compared with usual care; the patients in the home-based arm also had lower readmission rates than the patients receiving either usual care or the hospital rehabilitation programme.³⁴ Marchionni and colleagues reported improvements in total work capacity in patients of all ages randomised to the home- and hospital-based CR programmes, but not the usual care group. Health-related quality of life, measured by the Sickness Impact Profile, improved in all the groups.⁹⁵ DeBusk and colleagues compared short- and long-duration rehabilitation programmes in a hospital setting, at home monitored by telemetry and in a no-exercise training group.^{28,29,31} Peak functional capacity improved significantly in all the groups receiving exercise training, but not in the no-exercise group.

In addition, the changes in risk factors over the year of follow-up in this study are greater than those seen in the control arms of some RCTs of CR compared with usual care and similar to the changes in the intervention arms.^{32,34,35,143,144} Both Allen¹⁴³ and Heller and colleagues¹⁴⁴ report a similar rate of smoking cessation to that seen in the BRUM study in their intervention groups. We

found a greater fall in TC than in the control arms of Bell³⁴ and the SCRIP trial¹⁴⁵ and a greater fall in the HADS anxiety score than the control arm of Lewin and colleagues,³⁵ but a similar fall to that in the control arm of Bell³⁴ and Higgins and colleagues.³² Published randomised comparisons of home-based comprehensive CR with usual care have mixed results of the change in exercise capacity from baseline to follow-up. Both Bell³⁴ and Marchionni and colleagues⁹⁵ reported greater improvements in exercise capacity in the centre- and home-based arms, with a lesser improvement in the control arm, whereas in the SCRIP trial the improvement was similar in the control and rehabilitation arms.¹⁴⁵ Our study did not have a baseline value for exercise capacity, but we did find a significant ($p < 0.01$) improvement in self-reported physical activity (modified Godin score) in both the home- and centre-based arms from baseline to 1-year follow-up.

Generalisability

This was a pragmatic trial, with participants randomised to an invitation to a particular rehabilitation setting, to mirror the normal situation. Hence, 28% of the participants randomised to the centre-based rehabilitation did not commence CR. This is a lower level of non-participation than reported for the UK as a whole,^{36,146} which suggests that we had a more motivated group of participants than would occur outside a trial setting. The trial was largely set in a deprived inner-city location with a high proportion of ethnic minorities, particularly of South Asian origin. About 20% of our participants were from an ethnic minority group and as people of South Asian ethnicity have a high rate of cardiovascular disease¹⁴⁷⁻¹⁴⁹ this increases the generalisability of our study. The study had no upper age limit and the participants had a mean age of 61 years, which is similar to that reported in the survey undertaken by the British Association of Cardiac Rehabilitation.³⁶

The hospital-based programmes in our study were representative of those provided in England by a national survey.²⁶ Our programmes lasted from 6 to 12 weeks, which is similar to the 4–12 weeks identified by the survey, and consisted of 9–24 sessions, again comparing well with the 6–24 sessions found in the survey. All our hospitals provided the educational component by group talks, which is in keeping with the predominant model of provision in England, and provided a length of supervised exercise which lay within the

range for English programmes.²⁶ One of the hospitals (Hospital 2) experienced a major fire at the start of the trial, which resulted in the loss of the rehabilitation gym and the need to use less satisfactory premises. The original plans to increase the programme to twice weekly had to be delayed, and did not occur during the study period.

Home-based exercise was considered suitable for 61% of all patients presenting to the recruiting hospitals following MI, PTCA or CABG. Eligibility rates varied by presenting diagnosis, with 86.6% of patients post-CABG eligible, 66.5% of post-PTCA patients and only 53% of patients following MI. This last figure is very similar to the proportion of patients considered eligible for home CR following an MI by Bell³⁴ (56%). In our multi-ethnic inner-city population, only 44% of eligible patients agreed to participate compared with 82% in the populations studied by Bell. However, we did not find a difference in the deprivation level, measured by the IMD,¹⁵⁰ of those who agreed to recruitment compared with those who declined, although this must be interpreted with caution given the potential for ecological fallacy when attributing the IMD to an individual. We found no difference in the proportions agreeing to participate by diagnosis, but a significantly lower proportion of women agreed to participate (38% versus 46% of men, $p < 0.05$) and people aged over 65 years (37% versus 49% of those less than 65 years old, $p < 0.001$). Although patients from ethnic minority groups were less likely to be eligible to take part, largely due to an inability to support the language requirements, there was no difference in recruitment rates of eligible patients between white, South Asian and other ethnic groups.¹⁵¹ When a logistic regression was undertaken to identify which factors influenced recruitment, only age was significant.

The loss to follow-up in the trial was low and similar in both groups, with follow-up rates of live participants of 93% at 6 months, 91.5% at 1 year and 89% at 2 years. In addition, we had data about whether patients were still living for 98% of the participants at 2 years. The non-responders were significantly younger, had higher BMIs and higher HADS depression scores at baseline and were more likely to have been smokers at baseline, although this was not a significant difference. The loss to follow-up was very similar in both arms, so is unlikely to have introduced significant bias in our between-group analyses. The one outcome measure for which we had a higher level of missing data was for the exercise test (ISWT), with

participants not undertaking the test for a mixture of cardiovascular and musculoskeletal problems. An analysis substituting missing with imputed data resulted in the lessening of the non-significant differences in the ISWT, making it unlikely that we missed any significant differences between the home- and centre-based groups.

Our findings may not be generalisable to countries with more intensive centre-based programmes. However, there is little information about the comparative provision of CR across Europe. A survey undertaken in 1995 across 13 European countries revealed marked differences in the duration, content and intensity of the CR services.¹⁵²

Ethnic minority issues

Ethnic minority participation

People of South Asian ethnicity have a higher incidence rate of cardiovascular disease.^{147,148} To ensure the generalisability of the results of this study to the UK population, it is important to have a study population that represents that of the communities in which the rehabilitation would be provided.^{153,154} Given concerns about the lower uptake of CR in people from ethnic minority groups, we wanted to explore whether the provision of a home-based programme might improve uptake and adherence in this group. There have been concerns about the under-representation of people from ethnic minority groups in clinical trials^{153,155} and trials of cardiac patients in particular,¹⁵⁶ but few trials of CR have even reported the ethnicity of their participants. Exclusion of ethnic minorities from clinical trials undermines the UK Government's NHS plan for tackling inequalities and its core principle of providing culturally appropriate and accessible care for different groups and individuals.^{157,158} We achieved a recruitment of 20% of our participants from an ethnic minority group.

To achieve this rate of recruitment we undertook a number of special measures. We appointed two research nurses who spoke Punjabi, which is the most frequently spoken minority language in the location where the study took place. We also translated and recorded the information on the patient information leaflet into Punjabi to ensure that the information was provided accurately and consistently. As the home-based intervention required the use of a manual, we produced an abridged version of the Heart Manual in Punjabi and had this recorded. Participants who were

allocated to the home-based programme and who had a poor grasp of English were given the taped Punjabi version and a copy of the English manual. An English-speaking relative was encouraged to work through the manual on a weekly basis with the patient. One of our main outcomes was the HADS, which had not been adequately translated and validated for use in a British Punjabi-speaking population. We undertook a study prior to the start of BRUM to translate and validate the HADS in Punjabi.¹⁵⁹ We used recorded information because a significant proportion of ethnic minorities who are unable to read English are also unable to read their main language.¹⁰⁴

Despite these various measures, we still lost 29% of the ethnic minority patients who presented due to ineligibility for language reasons. In many cases this was because they spoke another minority language, which we were unable to support. Some Punjabi-speaking patients were lost during absences of the Punjabi-speaking staff. Of those patients recruited, only 10 considered that they needed an interpreter to complete the questionnaire, and 25 (4.7%) admitted that they were unable to read English or could read it only slightly and therefore needed the questions to be administered orally. Some 9% of our recruits spoke Punjabi as their main language.

The participants who were from an ethnic minority group were younger than the white recruits (mean age, white participants 62 years, other ethnic groups 56 years, $p < 0.001$) and less likely to be female (16% versus 25% of the white recruits). The ethnic minority participants also had a higher level of cardiac risk factors at baseline. They were more likely to be diabetic, with 26.4% of the ethnic minority participants reporting a history of diabetes, compared with only 10.4% of the white ethnic group ($p < 0.001$). The mean diastolic blood pressure was higher in the ethnic minority participants and they were also more likely to score highly on the HADS depression scale, with 12.7% of the ethnic minority participants having probable depression (a score of 11 or more), compared with only 4.4% of the white participants ($p < 0.05$). Depression is associated with poor outcomes following a cardiac event, with a higher incidence of cardiac-related morbidity and mortality,^{108,160} and is also associated with a lower adherence to CR and physical activity.^{161,162} Turner and colleagues followed up 1902 British CR participants and found that people with borderline or clinical depression (a score of 8–10 or 11+, respectively, on the HADS) were twice as likely to drop out of

their rehabilitation programme.¹⁶¹ Given the higher levels of risk factors in the ethnic minority participants, it is particularly important to ensure that CR is accessible and acceptable. A small study in the USA also found a higher prevalence of cardiac risk factors in black women compared with white women entering a CR programme⁵⁹ and Lip and colleagues, reporting on a patient sample from the same location as the BRUM study, reported lower levels of physical activity in South Asian patients admitted following MI.¹⁰⁰ The levels of adherence to CR among the ethnic minority participants in BRUM are discussed below.

Adherence

Adherence was measured by a modified Godin questionnaire at three time points, 6, 9 and 12 weeks after recruitment. At all three time points the ethnic minority participants reported a lower score and fewer hours of physical activity than the white participants. Given the relationship between physical activity adherence and depression and age, a regression analysis was undertaken adjusting for age, gender and HADS depression score at recruitment. The ethnic minority participants had significantly lower physical activity exercise scores at all three time points and fewer hours of self-reported physical activity at 6 and 9 weeks compared to the white participants. Cannistra and colleagues also found a lower adherence rate to CR among black than white women.⁵⁹

Outcomes

The low levels of physical activity prior to their cardiac event and during the rehabilitation period also occurred at 6 and 12-months of follow-up, with significantly shorter distances achieved on the ISWT by the ethnic minority participants. However, there was no interaction between ethnicity and the rehabilitation group, so both programmes produced similar outcomes in the ethnic minority participants. The ethnic minority participants also had significantly higher HADS anxiety and depression scores but lower SBP at the 1-year follow-up.

Qualitative study findings

Non-adherers to cardiac rehabilitation

The qualitative study found that many people who do not adhere to a formal programme of CR undertake their own modified programme of exercise and lifestyle change adapted from information provided by the CR nurses. Several patients changed to their own preferred exercise

programme rather than completing the CR programme, as even limited participation had given them the understanding of the importance of exercise and the confidence to exercise independently. This should be welcomed, but these patients would be labelled as non-attendees/adherers by a normal rehabilitation service. A study which compared an intensive hospital programme with a modified programme which facilitated independent exercise found that patients on the modified programme had higher exercise adherence at 6 months.⁹⁷

CR also encourages long-term maintenance of lifestyle changes. Patients who were unable to exercise at the level recommended in their CR programme were able to follow the advice on lifestyle changes. The changes undertaken by many of the patients in our study are consistent with patients resuming control of their recovery and lifestyle. Patients understood exercising “as being active” and some described this in terms of “not sitting in front of the TV all day”. Women in particular who had resumed household chores stressed the importance of being able to do these activities.

Patients’ reasons for not adhering to their CR programme were multifactorial and very individual. We identified some trends in the reason for non-adherence by socio-demographic characteristics: age, gender and ethnic group. In keeping with Halm and colleagues,¹⁶³ we found that women offered more reasons for their non-adherence. This has clinical implications in trying to encourage women to attend, as many potential obstructions will be presented. Women on the home-based programme reported a lack of motivation to be a problem, which may explain a study in which women were reported to have poorer outcomes from a home-based study, due to lower exercise adherence.¹⁶⁴ We identified that ethnic minority patients more frequently cited cardiac or other health problems as a factor contributing to their non-adherence. Tod and colleagues also identified ill-health as a cause of non-adherence to CR in patients of South Asian ethnicity.⁶⁰

Some patients had adapted the programme to suit their own needs because of co-morbidity or personal circumstances and were exercising at a low level not likely to reproduce the benefits found in randomised trials. Women, in particular, were more likely to describe the resumption of domestic tasks as a replacement for formal exercise. There is a difference between lay understanding of

exercise and the medical model. Early CR programmes were targeted at middle-aged men with less co-morbidity and as a wider range of patients take part in CR, particularly older patients and those with a lower level of fitness prior to their cardiac event, it is unrealistic to expect that they will all achieve the same level of exercise as in early studies. The benefits of CR are wider than taking part in formal exercise sessions as the programmes are a source of reliable and relevant information and help patients to make changes to their lifestyle to improve their health and reduce the risk of further cardiac events. The patients who dropped out of the hospital-based programme because they were unable to exercise also missed out on the education component of the programme, although many had clearly benefited from any sessions they had attended and from information they had been given. These patients might have benefited from continuing to attend the education and relaxation components of the programme and from the support of staff and other patients. In a study of women recovering from an MI, the key unmet need was for reliable information.¹⁶⁵

Our study has confirmed previous findings about patients' lack of knowledge and understanding of CR prior to entry into a programme. As awareness of the benefits of participation increases through the personal experiences of family and close friends, patients may view CR as an essential part of their treatment rather than an 'optional extra' for younger and fitter patients and this may increase participation. Two studies which targeted patients prior to their first CR appointment in order to reinforce the message about the benefits of CR both increased attendance rates.^{166,167}

The patients interviewed for this study were participants in an RCT and so had no choice in the programme to which they were initially randomised. Some patients were allocated to a programme which they did not want to do or was inappropriate for their needs and it meant they were unable to participate fully and were deemed to be non-adherers.

Patients who adhered to cardiac rehabilitation

Amongst the patients who adhered to their CR programme, there was little diversity of views amongst patients from each programme. In particular, patients in the hospital-based programme enjoyed the camaraderie of group exercise and the home-based patients valued the wealth of information and advice in the Heart

Manual, which gave them a feeling of being in control of their health. Hospital-based patients in the focus groups appeared to have a rapport with each other which the home-based patients did not have. This supports their view that one of the important benefits of the hospital-based programme is the support which patients get from exercising together and sharing their experiences of heart disease.

Barriers to participation seemed less important to patients who completed CR. The adherers on the hospital-based programme did not have major problems with transport and had convenient access by public transport although several patients on the home-based programme would have found it very difficult to attend the hospital-based programme because of transport difficulties and randomisation to the home programme had enabled them to complete a CR programme. Patients who had returned to work said that they were able to fit their exercise programme around their work and had sympathetic employers.

The patients in the focus groups who completed CR differed from the non-adherers interviewed in the BRUM trial in that they had fewer additional health problems which limited their ability to exercise. The patients who completed their programme took a pragmatic approach to working around any problems they did have and persevered with what they were able to do. The adherers also appeared more positive about their recovery and their general health than the non-adherers.

Patients who attended the focus group who were attending a continuation programme based at one of the hospitals had become dependent on this and were reluctant to exercise outside this environment. This shows the importance of helping patients to incorporate exercise into their daily lives so that exercise is not seen as just a form of treatment.

Theoretical approaches to qualitative findings

The insights that the qualitative study has given into patients' reasons for adherence to, non-adherence to and non-participation in CR suggest two useful perspectives through which differing behaviours could be viewed and explored in future research. Many patients who would have been termed by healthcare professionals non-adherers to or non-participants in CR, because of their behaviour around the formal programme, had nevertheless constructed their own informal 'rehabilitation'. This links in with work describing

how patients with chronic illness develop and continually adapt their own strategies for self-care which suit their social, psychological and physical situation at the time.^{168,169} Patients are often reluctant to discuss self-care strategies with healthcare professionals¹⁷⁰ and our study highlights the importance of exploring patients' informal health behaviours.

It is important to remember that rehabilitation constitutes only one stage of a patient's experience of a cardiac event. This was very apparent in patients' accounts, in which they graphically described the cardiac event itself, the impact it had on themselves and their family and the implications for their future lifestyle. This reflects Frank's work on patient narratives,¹⁷¹ which has been used as a way of explaining the experiences of patients with chronic illness.¹⁷² Patients interviewed in our study exemplified all three of Frank's types of narrative in their descriptions of their cardiac event and subsequent experiences; 'restitution' where a previously healthy individual has been ill but has positive expectations for their future health, 'chaos' where the patient's illness has caused such disruption that they have negative views of any future improvement in their situation and 'quest' where the illness has made the patient realise they need to make changes to their lifestyle.¹⁷¹ Thus patients who use 'restitution' or 'quest' narratives may be much more open to rehabilitation than those with 'chaos' narratives who do not anticipate any potential benefits. A consideration of the type of narrative that patients use to talk about their cardiac event may therefore help to explain their adherence behaviour regarding both formal and informal rehabilitation.

Limitations of the qualitative studies

A limitation of this qualitative work is that only patients who had consented to take part in a trial of CR, who were therefore expecting to have to exercise, were interviewed and the findings cannot be generalised to patients who declined to take part in the trial, who may have been less willing or able to exercise. Although many of the reasons identified in the interviews for not attending a programme may also apply to non-participants in the trial, it is likely that non-participants received less information and support in their recovery and were less motivated to exercise and make lifestyle changes.

Information needs

For the hospital-based patients, the interest in education sessions on medication and their comments that patients asked lots of questions

during these sessions suggest that medication is an area where patients need more information. This may be due to limited information in the public domain in an easily accessible format which patients can understand. Patients may be reluctant to ask their GP or pharmacist about side-effects and other aspects of how best to take their medication.

South Asians and lifestyle change

British Asians have been reported to undertake low levels of physical activity^{42,173} and have a high consumption of fatty food.¹⁷⁴ The Asian patients we interviewed showed an understanding of the advice about eating a healthier diet and were making significant changes to their diet. The difficulties that patients reported in making dietary and other lifestyle changes which were found in another study¹⁷⁵ were also seen in our study.

Healthcare implications

Important aspects of recent developments in the NHS are patient choice¹⁷⁶ and self-care.^{147,177} This qualitative study showed that many patients were willing and able to adopt self-care behaviours to improve their long-term health. Patients would benefit from a choice of a home- or hospital-based CR programme, and also from being able to change programmes if their initial preference did not suit their needs, as informed choice was not possible for many due to lack of knowledge. Patients could also be encouraged to participate in part of a programme rather than drop out completely if they are unable to take part in all aspects of a comprehensive CR programme.

Economic study findings

In comparing our economic results with those of previous studies, the greater size of our study is important. One important difference in the economic analysis reported here compared with previous studies^{34,95} is that no difference was found in subsequent service usage, but the size of these studies limited their power to detect such differences reliably. A lower subsequent health service use is difficult to interpret, as it might reflect a better health status in patients in the home-based programmes, or unmet need, with problems not dealt with in a timely manner.

In the present study, the home-based CR had a higher healthcare mean cost than the centre-based arm, again in contrast with previous studies, and due largely to the lack of savings due to reduced

health service utilisation seen in previous studies. However, when patient costs concerned with travel to the hospital were included, the differences were no longer significant. Previous studies did not include such patient costs, although guidelines for economic evaluation generally recommend inclusion of such costs. Failure to include such costs hides a shifting of costs to patients. In addition, the majority of previous economic analyses had a more intensive centre-based programme than are standard in the UK^{28,29,31,95,97,98} and had less home visiting than was provided in this study.¹⁰⁰ Although the cost per patient in the centre-based arm in BRUM was lower than in the HTA survey⁶³ (£157 in BRUM versus £220 per patient referred), much of this difference is due to the BRUM centre-based costs including a narrower range of services and focusing on Phase III of the CR programme whereas the HTA survey included the whole CR service costs divided between the number of CR participants. This will include the phase one input to all patients, some Phase II home visiting programmes and some Phase IV continuation programmes. In addition, some CR programmes provide support to a wider range of patient diagnoses than included in this study.²⁶ When the centre-based rehabilitation service in BRUM is compared with the less intensive forms of CR in the HTA survey, the cost difference decreases.

The higher CR costs in the home-based arm must be seen in the context of a higher uptake of CR in that arm, with 96% of patients receiving five or more contacts with a CR nurse. This contrasts with 28% of the patients referred to the centre-based programme failing to attend any CR session and a further 8% attending only once. Were patients to attend all the planned sessions in the hospital-based programmes, the costs to the NHS are of a similar order to those of the home-based programme for the three lower intensity programmes (£115–193 for the hospital- and £198 for the home-based programme) and potentially considerably more for the centre with 24 planned sessions (£380).

Potential limitations of the economic analysis are the heterogeneity of services and costs within the centre-based arm and with travel costs that were estimated rather than reported. The centre-based arm comprised four hospitals with three different target numbers of rehabilitation sessions. Approximately one-quarter of the centre-based patients attended the hospital that had a relatively high number of planned sessions. In addition, patients in the centre-based arm were more likely to attend a Phase IV CR programme, after the end

of their standard CR programme, and this was not included in the costing. However, the centre with the most active Phase IV programme was the most costly (Hospital 1). The study was not powered to undertake analyses at the individual centre level, but we have presented results of the costs and outcomes by three centre-based groups. This shows that Hospital 1, which had the most planned sessions, had significantly higher costs than the other two centres and similar to that of the home-based programme. If borne out in a larger sample of patients, this suggests that the relative costs between home- and hospital-based programmes will depend on the intensity of the hospital programmes and travel time of the staff providing the home-based programme.

Patient travel costs mattered in the centre-based arm, but were estimated on the basis of distance from hospital combined with a best estimate of private car cost per kilometre. Although patients were asked in a postal survey about costs incurred as a result of their rehabilitation programme, relatively few responded, with only 88 (34%) of the centre-based participants citing travel costs. We are also aware that some patients attending the hospital CR programmes received hospital transport, but we have no information about the numbers affected. This would, however, increase the costs in the centre-based arm. The small difference between the home- and centre-based costs makes the societal costs sensitive to travel and weekly parking charges, which we did not estimate.

It is likely that there was some measurement error in the recording of the number of hospital attendances at CR as, in keeping with previous reports of poor maintenance of CR records,²⁶ we found some disagreement between the computerised and paper case notes.

Conclusions

The BRUM study did not find any significant differences in objective cardiac risk factors at 6, 12 or 24 months following a cardiac event between patients who were randomised to receive a home-based CR programme (Heart Manual) and patients randomised to receive a centre-based programme. There was no difference between the study arms in the number of participants who had a subsequent cardiac event (MI/revascularisation/death) by 2 years of follow-up. During the early rehabilitation period, self-reported physical activity was higher in the home-based arm, and this was the case for

older patients and ethnic minorities, but not women. However, this difference in self-reported activity was gone by the 6-month follow-up. There was no interaction between the type of rehabilitation programme and a number of prespecified patient characteristics: age, sex, initial diagnosis, ethnicity and hospital of recruitment.

From the perspective of the NHS, provision of the home-based programme was £41 (95% CI £26 to £55) higher per patient, but there was no difference when a patient's travel and time off work costs were taken into account.

The qualitative study found that many people who do not adhere to a formal programme of CR undertake their own modified programme of exercise and lifestyle change adapted from information provided by the CR nurses. The reasons for non-participation/non-adherence were multifactorial and individualistic, and in most cases one critical factor determined eventual CR behaviour. There were differences in the reasons given by home- and hospital-based CR patients, with home-based patients often citing a lack of motivation to exercise at home, particularly women. Domestic duties in women and ill-health in ethnic minority patients were also common reasons for non-adherence.

Relevance of findings to the NHS

The main quantitative study found no difference in clinical outcomes for patients of low to moderate risk after a cardiac event in home- and centre-based CR programmes. Hospital-based programmes are necessary for patients considered at high risk during physical activity, but with the expansion of CR provision to patients post-revascularisation and with heart failure there is often a shortage of gymnasium time such that programmes could not provide the service should all eligible patients wish to attend.²⁶ Provision of a home-based CR programme alongside a centre-based service would probably enable a higher proportion of cardiac patients to benefit from CR, without compromising the quality of service offered to patients.

The qualitative studies revealed a high level of satisfaction among patients who adhered to both the home- and centre-based programmes, but motivation, personal circumstances and travel difficulties were important factors in the decisions of patients who did not attend or adhere to a CR programme. This highlights the importance of

choice for patients to determine which programme will most suit their personal circumstances and motivational state and to be able to change programmes should they find that their chosen programme does not suit. Following up patients who do not take up or who drop out of a CR programme, with the offer of an alternative programme, may improve participation rates. In addition, when we looked at whether there was any relationship between the home- or centre-based programme and the characteristics of the participants, we found none. We have no evidence to suggest that a particular socio-demographic characteristic such as age, gender, ethnicity or the initial type of cardiac event can be used to target a particular CR programme to an individual.

We identified a decline in exercise capacity from the 6-month assessment through the 1 and 2-year assessments. We had hoped that the home-based programme would enable patients to build physical activity into their daily life and thus maintain this activity in the long term. However, their last contact with a CR nurse was 12 weeks post-cardiac event and it appears that some form of reinforcement is needed to encourage them to continue with their lifestyle changes. This could take the form of more Phase IV programmes or telephone support and could be undertaken from secondary or primary care.

Research has highlighted the budgetary constraints affecting most CR programmes in England.²⁶ Many CR departments are not providing an adequate service and are understaffed for the minority of patients to whom they do provide CR. Resources are often tied up in staff costs and it is difficult for them to find the funds to purchase the Heart Manuals. However, the focus groups with patients who adhered to the home-based programme identified that they considered the Heart Manual to be a valuable source of information.

In our study, the home-based programme was more costly than the centre-based programme, although the uptake of the former was much greater. It is possible that as the CR nurses gained more experience with the Heart Manual the duration of their visits would have been shorter, but a large proportion of their time was travel and the associated difficulties of parking on a hospital site. As they were also recruiting patients to the study, their time might have been used less efficiently than a dedicated nurse providing the home support. Basing CR staff who provide home visiting in an accessible community location would reduce staff costs associated with travelling and parking.

Recommendations for research

Measuring psychological health and quality of life in ethnic minority patients

Many standard questionnaires have not been translated and adequately validated in minority languages. We cannot monitor or compare outcomes in ethnic minority patients without adequate tools and there is a need for this to be undertaken.

Dietary and physical activity assessment tools

Design and validation of short dietary and physical activity questionnaires for self-completion suitable to use in a UK cardiac population are required. Many of the standard physical activity questionnaires are age or culturally specific or designed for epidemiological studies.

Exploring differences in outcomes from different cardiac rehabilitation programmes

Although we found no evidence of an interaction between the treatment arm (home versus centre based) and the centre of recruitment, we did not have the power to explore subgroup differences fully. Further research could explore the outcomes of home versus centre-based CR in larger samples of more and less intensive centre-based CR programmes.

Use of the Heart Manual in patients who decline centre-based cardiac rehabilitation programmes

It is possible that the Heart Manual could improve the uptake of CR by patients who decline centre-based CR programmes. This study found a very high rate of acceptance of home visits in patients

allocated to the home-based programme and it needs to be explored whether similar findings, and changes in lifestyle behaviours, would result from the use of the Heart Manual in a group who decline centre-based CR.

Cardiac rehabilitation provision to ethnic minority patients

The ethnic minority participants in this study presented with higher levels of risk factors and did not achieve the same health gains as the majority white participants and reported lower levels of physical activity during the CR period. Research needs to be undertaken to determine how we can improve the exercise capacity of the ethnic minority patients, possibly by offering extended or more intensive programmes or more Phase IV CR programmes.

To evaluate the implementation of home-based cardiac rehabilitation programmes in the UK

With the addition of home-based CR programmes as part of standard care in hospitals, the uptake of and adherence to CR in a non-trial based, normal clinical population could be evaluated to determine whether more patients are reached.

Evaluation of strategies that sustain physical activities in the long term

This study showed a fall-off in exercise capacity over the duration of the trial. The maintenance of activity is being investigated through Phase IV CR programmes and this evidence needs to be systematically reviewed. In addition, research is needed to consider ways of reducing this decline in exercise capacity for all patients, including those who do not want or are unable to attend a formal exercise session long term.



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Kate Jolly (Senior Lecturer in Public Health and Epidemiology), Gregory Lip (Professor of Cardiovascular Medicine), Andrew Stevens (Professor of Public Health), Jonathan Mant (Senior Lecturer in Primary Care), Sheila Greenfield (Senior Lecturer in Medical Sociology), Deirdre Lane (Lecturer in Medicine) and James Raftery (Professor of Health Economics) conceived the study, wrote the original grant proposal and were members of the trial management group. Trial implementation was undertaken by KJ and KL. Analysis was largely undertaken by KJ with support from Rod Taylor (Reader in Public Health), who was also a member of the trial management group. Economic analysis was undertaken by JR with support from KJ, RL and RT. The qualitative studies were undertaken by SG, KJ and Miren Jones, who drafted the qualitative chapter of the report. The report was drafted by KJ; all authors contributed to the final text.



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Appendix I

Dietary questionnaire

In the last four weeks, about how often did you eat a serving of the following foods?
(circle one number for each food type)

(i) Fresh fruit, fresh or frozen vegetables or salad vegetables	Never	0
	Less than once/week	1
	1–3 days a week	2
	4–6 days a week	3
	1–2 times a day	4
	3–4 times a day	5
	More than 4 times a day	6
<i>a serving =</i>		
	<i>1 piece of fresh fruit</i>	
	<i>2 tablespoons of vegetables</i>	
	<i>2 tablespoons of tinned or stewed fruit</i>	
	<i>a small dessert bowl of salad</i>	
(ii) Fish (not fried)	Never	0
	Less than once/week	1
	1–3 days a week	2
	4–6 days a week	3
	1–2 times a day	4
	3–4 times a day	5
	More than 4 times a day	6
(iii) Any fried food, including fried fish, chips, cooked breakfast, samosas or ghee used in cooking	Never	0
	Less than once/week	1
	1–3 days a week	2
	4–6 days a week	3
	1–2 times a day	4
	3–4 times a day	5
	More than 4 times a day	6
(v) Chicken or turkey, including processed chicken or turkey	Never	0
	Less than once/week	1
	1–3 days a week	2
	4–6 days a week	3
	1–2 times a day	4
	3–4 times a day	5
	More than 4 times a day	6

(vi) Beef, pork or lamb, including beefburgers, sausages, bacon, meat pies and processed meat	Never	0
	Less than once/week	1
	1–3 days a week	2
	4–6 days a week	3
	1–2 times a day	4
	3–4 times a day	5
(vii) Chocolate, crisps or biscuits, including savoury biscuits	More than 4 times a day	6
	Never	0
	Less than once/week	1
	1–3 days a week	2
	4–6 days a week	3
	1–2 times a day	4
3–4 times a day	5	
More than 4 times a day	6	

Appendix 2

Unit costs to be used in CHD treatment model, England 2000–1

Type of case	HRG/reference/use	Unit cost (£)	Comments
Primary care costs			
GP first consultation (one-off)	Netten and Curtis ¹³⁴	30	Assume cost of GP and nurse
Follow-up consultation (continuous)	Netten and Curtis ¹³⁴	20	Assume all CHD patients have 6-monthly visits. Includes CHD clinics and providing repeat prescriptions
Drug regimens – GP (all continuous)		£/patient/year	
Calcium channel blockers	DDD	130	Proportion of all patients
Beta-blockers	DDD	52	Proportion of all patients for symptoms, of post-MI patients for secondary prevention
ACE inhibitors	DDD	95	Proportion of all patients
Antiplatelet (aspirin)	DDD	20	Proportion of all patients
Nitrates	DDD	78	Proportion of patients
Statins	DDD	327	Proportion of all patients
Dispensing cost	All GP prescriptions	24	£2/dispensation, monthly
Outpatient visits (one-off or limited number)			
Assessment visits or chest pain clinic	E09op plus E13op	84	First outpatient visit for assessment, includes exercise ECG and pathology test
Follow-up attendance	E16op	54	Use for all follow-up outpatient attendances; assume 2 per first visit
Cardiothoracic surgery, first outpatient	OPF170	131	Assume prior to CABG
Cardiothoracic surgery, follow-up attendance	OPFU170	95	Assume two follow-up attendances for all CABGs
Day and inpatient episodes – all one-off			
Angiogram	E14 day case	657	This figure used for all angiograms (in practice 63% are day case)
CABG	E04 elective	5483	Add cardiothoracic outpatients above
	E04 non-elective	5558	For those with unstable angina or MI
PTCA	E15 elective	2428	As for CABG. Includes costs of stents and drugs
	E15 non-elective	2689	For those with unstable angina or MI
MI	E12 nelip	909	Add one day CCU/A&E admission ward for all, plus thrombolysis for proportion and angiogram/PTCA/CABG (?) where needed
Unstable angina	E33 nelip	741	Add CCU and angiogram/PTCA as for MI. No thrombolysis cost to be included
CCU/chest pain clinic/A&E	CC7	298	Assuming all MI and UA admissions via this route. £399 (less thrombolysis cost of £202/2)
Thrombolysis, streptokinase, alteplase		202	83% streptokinase at £85.45 per dose and 17% alteplase at £770 per dose, as per UKHAS study

continued

Type of case	HRG/reference/use	Unit cost (£)	Comments
Other services			
Ambulance	Scenario		Ambulance costs have been based on increase in annual funding 1997-2003 of £18 million p.a.
Cardiac rehabilitation	HTA report	486/course	Assume offered to all CHD patients post-hospital. Different take-up rates for AMI for UA, CABG and PTCA. See working paper T10 for further details
<p>A&E, accident and emergency; CCU, coronary care unit; DDD, defined daily dose; HRG, health resource group; UA, unstable angina. Source: Davies R, Normand C, Raftery J, Roderick P, Sanderson C. <i>Policy analysis for coronary heart disease: a simulation model of interventions, costs and outcomes</i>. Report to Department of Health; 2004.</p>			



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Factors that limit the quality, number and progress of randomised controlled trials.

A review by Prescott RJ, Counsell CE, Gillespie WJ, Grant AM, Russell IT, Kiauka S, *et al.*

No. 21

Antimicrobial prophylaxis in total hip replacement: a systematic review.

By Glenny AM, Song F.

No. 22

Health promoting schools and health promotion in schools: two systematic reviews.

By Lister-Sharp D, Chapman S, Stewart-Brown S, Sowden A.

No. 23

Economic evaluation of a primary care-based education programme for patients with osteoarthritis of the knee.

A review by Lord J, Victor C, Littlejohns P, Ross FM, Axford JS.

Volume 4, 2000

No. 1

The estimation of marginal time preference in a UK-wide sample (TEMPUS) project.

A review by Cairns JA, van der Pol MM.

No. 2

Geriatric rehabilitation following fractures in older people: a systematic review.

By Cameron I, Crotty M, Currie C, Finnegan T, Gillespie L, Gillespie W, *et al.*

No. 3

Screening for sickle cell disease and thalassaemia: a systematic review with supplementary research.

By Davies SC, Cronin E, Gill M, Greengross P, Hickman M, Normand C.

No. 4

Community provision of hearing aids and related audiology services.

A review by Reeves DJ, Alborz A, Hickson FS, Bamford JM.

No. 5

False-negative results in screening programmes: systematic review of impact and implications.

By Petticrew MP, Sowden AJ, Lister-Sharp D, Wright K.

No. 6

Costs and benefits of community postnatal support workers: a randomised controlled trial.

By Morrell CJ, Spiby H, Stewart P, Walters S, Morgan A.

No. 7

Implantable contraceptives (subdermal implants and hormonally impregnated intrauterine systems) versus other forms of reversible contraceptives: two systematic reviews to assess relative effectiveness, acceptability, tolerability and cost-effectiveness.

By French RS, Cowan FM, Mansour DJA, Morris S, Procter T, Hughes D, *et al.*

No. 8

An introduction to statistical methods for health technology assessment.

A review by White SJ, Ashby D, Brown PJ.

No. 9

Disease-modifying drugs for multiple sclerosis: a rapid and systematic review.

By Clegg A, Bryant J, Milne R.

No. 10

Publication and related biases.

A review by Song F, Eastwood AJ, Gilbody S, Duley L, Sutton AJ.

No. 11

Cost and outcome implications of the organisation of vascular services.

By Michaels J, Brazier J, Palfreyman S, Shackley P, Slack R.

No. 12

Monitoring blood glucose control in diabetes mellitus: a systematic review.

By Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R.

No. 13

The effectiveness of domiciliary health visiting: a systematic review of international studies and a selective review of the British literature.

By Elkan R, Kendrick D, Hewitt M, Robinson JJA, Tolley K, Blair M, *et al.*

No. 14

The determinants of screening uptake and interventions for increasing uptake: a systematic review.

By Jepson R, Clegg A, Forbes C, Lewis R, Sowden A, Kleijnen J.

No. 15

The effectiveness and cost-effectiveness of prophylactic removal of wisdom teeth.

A rapid review by Song F, O'Meara S, Wilson P, Golder S, Kleijnen J.

No. 16

Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women's views.

By Bricker L, Garcia J, Henderson J, Mugford M, Neilson J, Roberts T, *et al.*

No. 17

A rapid and systematic review of the effectiveness and cost-effectiveness of the taxanes used in the treatment of advanced breast and ovarian cancer.

By Lister-Sharp D, McDonagh MS, Khan KS, Kleijnen J.

No. 18

Liquid-based cytology in cervical screening: a rapid and systematic review.

By Payne N, Chilcott J, McGoogan E.

No. 19

Randomised controlled trial of non-directive counselling, cognitive-behaviour therapy and usual general practitioner care in the management of depression as well as mixed anxiety and depression in primary care.

By King M, Sibbald B, Ward E, Bower P, Lloyd M, Gabbay M, *et al.*

No. 20

Routine referral for radiography of patients presenting with low back pain: is patients' outcome influenced by GPs' referral for plain radiography?

By Kerry S, Hilton S, Patel S, Dundas D, Rink E, Lord J.

No. 21

Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration.

By O'Meara S, Cullum N, Majid M, Sheldon T.

No. 22

Using routine data to complement and enhance the results of randomised controlled trials.

By Lewsey JD, Leyland AH, Murray GD, Boddy FA.

No. 23

Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review.

By Meads C, Cummins C, Jolly K, Stevens A, Burls A, Hyde C.

No. 24

Outcome measures for adult critical care: a systematic review.

By Hayes JA, Black NA, Jenkinson C, Young JD, Rowan KM, Daly K, *et al.*

No. 25

A systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding.

By Fairbank L, O'Meara S, Renfrew MJ, Woolridge M, Sowden AJ, Lister-Sharp D.

No. 26

Implantable cardioverter defibrillators: arrhythmias. A rapid and systematic review.

By Parkes J, Bryant J, Milne R.

No. 27

Treatments for fatigue in multiple sclerosis: a rapid and systematic review.

By Brañas P, Jordan R, Fry-Smith A, Burls A, Hyde C.

No. 28

Early asthma prophylaxis, natural history, skeletal development and economy (EASE): a pilot randomised controlled trial.

By Baxter-Jones ADG, Helms PJ, Russell G, Grant A, Ross S, Cairns JA, *et al.*

No. 29

Screening for hypercholesterolaemia versus case finding for familial hypercholesterolaemia: a systematic review and cost-effectiveness analysis.

By Marks D, Wonderling D, Thorogood M, Lambert H, Humphries SE, Neil HAW.

No. 30

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of glycoprotein IIb/IIIa antagonists in the medical management of unstable angina.

By McDonagh MS, Bachmann LM, Golder S, Kleijnen J, ter Riet G.

No. 31

A randomised controlled trial of prehospital intravenous fluid replacement therapy in serious trauma.

By Turner J, Nicholl J, Webber L, Cox H, Dixon S, Yates D.

No. 32

Intrathecal pumps for giving opioids in chronic pain: a systematic review.

By Williams JE, Louw G, Towler G.

No. 33

Combination therapy (interferon alfa and ribavirin) in the treatment of chronic hepatitis C: a rapid and systematic review.

By Shepherd J, Waugh N, Hewitson P.

No. 34

A systematic review of comparisons of effect sizes derived from randomised and non-randomised studies.

By MacLehose RR, Reeves BC, Harvey IM, Sheldon TA, Russell IT, Black AMS.

No. 35

Intravascular ultrasound-guided interventions in coronary artery disease: a systematic literature review, with decision-analytic modelling, of outcomes and cost-effectiveness.

By Berry E, Kelly S, Hutton J, Lindsay HSJ, Blaxill JM, Evans JA, *et al.*

No. 36

A randomised controlled trial to evaluate the effectiveness and cost-effectiveness of counselling patients with chronic depression.

By Simpson S, Corney R, Fitzgerald P, Beecham J.

No. 37

Systematic review of treatments for atopic eczema.

By Hoare C, Li Wan Po A, Williams H.

No. 38

Bayesian methods in health technology assessment: a review.

By Spiegelhalter DJ, Myles JP, Jones DR, Abrams KR.

No. 39

The management of dyspepsia: a systematic review.

By Delaney B, Moayyedi P, Deeks J, Innes M, Soo S, Barton P, *et al.*

No. 40

A systematic review of treatments for severe psoriasis.

By Griffiths CEM, Clark CM, Chalmers RJG, Li Wan Po A, Williams HC.

Volume 5, 2001

No. 1

Clinical and cost-effectiveness of donepezil, rivastigmine and galantamine for Alzheimer's disease: a rapid and systematic review.

By Clegg A, Bryant J, Nicholson T, McIntyre L, De Broe S, Gerard K, *et al.*

No. 2

The clinical effectiveness and cost-effectiveness of riluzole for motor neurone disease: a rapid and systematic review.

By Stewart A, Sandercock J, Bryan S, Hyde C, Barton PM, Fry-Smith A, *et al.*

No. 3

Equity and the economic evaluation of healthcare.

By Sassi F, Archard L, Le Grand J.

No. 4

Quality-of-life measures in chronic diseases of childhood.

By Eiser C, Morse R.

No. 5

Eliciting public preferences for healthcare: a systematic review of techniques.

By Ryan M, Scott DA, Reeves C, Bate A, van Teijlingen ER, Russell EM, *et al.*

No. 6

General health status measures for people with cognitive impairment: learning disability and acquired brain injury.

By Riemsma RP, Forbes CA, Glanville JM, Eastwood AJ, Kleijnen J.

No. 7

An assessment of screening strategies for fragile X syndrome in the UK.

By Pembrey ME, Barnicoat AJ, Carmichael B, Bobrow M, Turner G.

No. 8

Issues in methodological research: perspectives from researchers and commissioners.

By Lilford RJ, Richardson A, Stevens A, Fitzpatrick R, Edwards S, Rock F, *et al.*

No. 9

Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy.

By Cullum N, Nelson EA, Flemming K, Sheldon T.

No. 10

Effects of educational and psychosocial interventions for adolescents with diabetes mellitus: a systematic review.

By Hampson SE, Skinner TC, Hart J, Storey L, Gage H, Foxcroft D, *et al.*

No. 11

Effectiveness of autologous chondrocyte transplantation for hyaline cartilage defects in knees: a rapid and systematic review.

By Jobanputra P, Parry D, Fry-Smith A, Burls A.

No. 12

Statistical assessment of the learning curves of health technologies.

By Ramsay CR, Grant AM, Wallace SA, Garthwaite PH, Monk AF, Russell IT.

No. 13

The effectiveness and cost-effectiveness of temozolomide for the treatment of recurrent malignant glioma: a rapid and systematic review.

By Dinnes J, Cave C, Huang S, Major K, Milne R.

No. 14

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention.

By Lewis R, Whiting P, ter Riet G, O'Meara S, Glanville J.

No. 15

Home treatment for mental health problems: a systematic review.

By Burns T, Knapp M, Catty J, Healey A, Henderson J, Watt H, *et al.*

No. 16

How to develop cost-conscious guidelines.

By Eccles M, Mason J.

No. 17

The role of specialist nurses in multiple sclerosis: a rapid and systematic review.

By De Broe S, Christopher F, Waugh N.

No. 18

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of orlistat in the management of obesity.

By O'Meara S, Riemsma R, Shirran L, Mather L, ter Riet G.

No. 19

The clinical effectiveness and cost-effectiveness of pioglitazone for type 2 diabetes mellitus: a rapid and systematic review.

By Chilcott J, Wight J, Lloyd Jones M, Tappenden P.

No. 20

Extended scope of nursing practice: a multicentre randomised controlled trial of appropriately trained nurses and preregistration house officers in pre-operative assessment in elective general surgery.

By Kinley H, Czoski-Murray C, George S, McCabe C, Primrose J, Reilly C, *et al.*

No. 21

Systematic reviews of the effectiveness of day care for people with severe mental disorders: (1) Acute day hospital versus admission; (2) Vocational rehabilitation; (3) Day hospital versus outpatient care.

By Marshall M, Crowther R, Almaraz-Serrano A, Creed F, Sledge W, Kluiters H, *et al.*

No. 22

The measurement and monitoring of surgical adverse events.

By Bruce J, Russell EM, Mollison J, Krukowski ZH.

No. 23

Action research: a systematic review and guidance for assessment.

By Waterman H, Tillen D, Dickson R, de Koning K.

No. 24

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of gemcitabine for the treatment of pancreatic cancer.

By Ward S, Morris E, Bansback N, Calvert N, Crellin A, Forman D, *et al.*

No. 25

A rapid and systematic review of the evidence for the clinical effectiveness and cost-effectiveness of irinotecan, oxaliplatin and raltitrexed for the treatment of advanced colorectal cancer.

By Lloyd Jones M, Hummel S, Bansback N, Orr B, Seymour M.

No. 26

Comparison of the effectiveness of inhaler devices in asthma and chronic obstructive airways disease: a systematic review of the literature.

By Brocklebank D, Ram F, Wright J, Barry P, Cates C, Davies L, *et al.*

No. 27

The cost-effectiveness of magnetic resonance imaging for investigation of the knee joint.

By Bryan S, Weatherburn G, Bungay H, Hatrick C, Salas C, Parry D, *et al.*

No. 28

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of topotecan for ovarian cancer.

By Forbes C, Shirran L, Bagnall A-M, Duffy S, ter Riet G.

No. 29

Superseded by a report published in a later volume.

No. 30

The role of radiography in primary care patients with low back pain of at least 6 weeks duration: a randomised (unblinded) controlled trial.

By Kendrick D, Fielding K, Bentley E, Miller P, Kerslake R, Pringle M.

No. 31

Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients.

By McColl E, Jacoby A, Thomas L, Soutter J, Bamford C, Steen N, *et al.*

No. 32

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of paclitaxel, docetaxel, gemcitabine and vinorelbine in non-small-cell lung cancer.

By Clegg A, Scott DA, Sidhu M, Hewitson P, Waugh N.

No. 33

Subgroup analyses in randomised controlled trials: quantifying the risks of false-positives and false-negatives.

By Brookes ST, Whitley E, Peters TJ, Mulheran PA, Egger M, Davey Smith G.

No. 34

Depot antipsychotic medication in the treatment of patients with schizophrenia: (1) Meta-review; (2) Patient and nurse attitudes.

By David AS, Adams C.

No. 35

A systematic review of controlled trials of the effectiveness and cost-effectiveness of brief psychological treatments for depression.

By Churchill R, Hunot V, Corney R, Knapp M, McGuire H, Tylee A, *et al.*

No. 36

Cost analysis of child health surveillance.

By Sanderson D, Wright D, Acton C, Duree D.

Volume 6, 2002**No. 1**

A study of the methods used to select review criteria for clinical audit.

By Hearnshaw H, Harker R, Cheater F, Baker R, Grimshaw G.

No. 2

Fludarabine as second-line therapy for B cell chronic lymphocytic leukaemia: a technology assessment.

By Hyde C, Wake B, Bryan S, Barton P, Fry-Smith A, Davenport C, *et al.*

No. 3

Rituximab as third-line treatment for refractory or recurrent Stage III or IV follicular non-Hodgkin's lymphoma: a systematic review and economic evaluation.

By Wake B, Hyde C, Bryan S, Barton P, Song F, Fry-Smith A, *et al.*

No. 4

A systematic review of discharge arrangements for older people.

By Parker SG, Peet SM, McPherson A, Cannaby AM, Baker R, Wilson A, *et al.*

No. 5

The clinical effectiveness and cost-effectiveness of inhaler devices used in the routine management of chronic asthma in older children: a systematic review and economic evaluation.

By Peters J, Stevenson M, Beverley C, Lim J, Smith S.

No. 6

The clinical effectiveness and cost-effectiveness of sibutramine in the management of obesity: a technology assessment.

By O'Meara S, Riemsma R, Shirran L, Mather L, ter Riet G.

No. 7

The cost-effectiveness of magnetic resonance angiography for carotid artery stenosis and peripheral vascular disease: a systematic review.

By Berry E, Kelly S, Westwood ME, Davies LM, Gough MJ, Bamford JM, *et al.*

No. 8

Promoting physical activity in South Asian Muslim women through 'exercise on prescription'.

By Carroll B, Ali N, Azam N.

No. 9

Zanamivir for the treatment of influenza in adults: a systematic review and economic evaluation.

By Burls A, Clark W, Stewart T, Preston C, Bryan S, Jefferson T, *et al.*

No. 10

A review of the natural history and epidemiology of multiple sclerosis: implications for resource allocation and health economic models.

By Richards RG, Sampson FC, Beard SM, Tappenden P.

No. 11

Screening for gestational diabetes: a systematic review and economic evaluation.

By Scott DA, Loveman E, McIntyre L, Waugh N.

No. 12

The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation.

By Clegg AJ, Colquitt J, Sidhu MK, Royle P, Loveman E, Walker A.

No. 13

The clinical effectiveness of trastuzumab for breast cancer: a systematic review.

By Lewis R, Bagnall A-M, Forbes C, Shirran E, Duffy S, Kleijnen J, *et al.*

No. 14

The clinical effectiveness and cost-effectiveness of vinorelbine for breast cancer: a systematic review and economic evaluation.

By Lewis R, Bagnall A-M, King S, Woolcott N, Forbes C, Shirran L, *et al.*

No. 15

A systematic review of the effectiveness and cost-effectiveness of metal-on-metal hip resurfacing arthroplasty for treatment of hip disease.

By Vale L, Wyness L, McCormack K, McKenzie L, Brazzelli M, Stearns SC.

No. 16

The clinical effectiveness and cost-effectiveness of bupropion and nicotine replacement therapy for smoking cessation: a systematic review and economic evaluation.

By Woolcott NF, Jones L, Forbes CA, Mather LC, Sowden AJ, Song FJ, *et al.*

No. 17

A systematic review of effectiveness and economic evaluation of new drug treatments for juvenile idiopathic arthritis: etanercept.

By Cummins C, Connock M, Fry-Smith A, Burls A.

No. 18

Clinical effectiveness and cost-effectiveness of growth hormone in children: a systematic review and economic evaluation.

By Bryant J, Cave C, Mihaylova B, Chase D, McIntyre L, Gerard K, *et al.*

No. 19

Clinical effectiveness and cost-effectiveness of growth hormone in adults in relation to impact on quality of life: a systematic review and economic evaluation.

By Bryant J, Loveman E, Chase D, Mihaylova B, Cave C, Gerard K, *et al.*

No. 20

Clinical medication review by a pharmacist of patients on repeat prescriptions in general practice: a randomised controlled trial.

By Zermansky AG, Petty DR, Raynor DK, Lowe CJ, Frementle N, Vail A.

No. 21

The effectiveness of infliximab and etanercept for the treatment of rheumatoid arthritis: a systematic review and economic evaluation.

By Jobanputra P, Barton P, Bryan S, Burls A.

No. 22

A systematic review and economic evaluation of computerised cognitive behaviour therapy for depression and anxiety.

By Kaltenthaler E, Shackley P, Stevens K, Beverley C, Parry G, Chilcott J.

No. 23

A systematic review and economic evaluation of pegylated liposomal doxorubicin hydrochloride for ovarian cancer.

By Forbes C, Wilby J, Richardson G, Sculpher M, Mather L, Reimsma R.

No. 24

A systematic review of the effectiveness of interventions based on a stages-of-change approach to promote individual behaviour change.

By Riemsma RP, Pattenden J, Bridle C, Sowden AJ, Mather L, Watt IS, *et al.*

No. 25

A systematic review update of the clinical effectiveness and cost-effectiveness of glycoprotein IIb/IIIa antagonists.

By Robinson M, Ginnelly L, Sculpher M, Jones L, Riemsma R, Palmer S, *et al.*

No. 26

A systematic review of the effectiveness, cost-effectiveness and barriers to implementation of thrombolytic and neuroprotective therapy for acute ischaemic stroke in the NHS.

By Sandercock P, Berge E, Dennis M, Forbes J, Hand P, Kwan J, *et al.*

No. 27

A randomised controlled crossover trial of nurse practitioner versus doctor-led outpatient care in a bronchiectasis clinic.

By Caine N, Sharples LD, Hollingworth W, French J, Keogan M, Exley A, *et al.*

No. 28

Clinical effectiveness and cost – consequences of selective serotonin reuptake inhibitors in the treatment of sex offenders.

By Adi Y, Ashcroft D, Browne K, Beech A, Fry-Smith A, Hyde C.

No. 29

Treatment of established osteoporosis: a systematic review and cost-utility analysis.

By Kanis JA, Brazier JE, Stevenson M, Calvert NW, Lloyd Jones M.

No. 30

Which anaesthetic agents are cost-effective in day surgery? Literature review, national survey of practice and randomised controlled trial.

By Elliott RA Payne K, Moore JK, Davies LM, Harper NJN, St Leger AS, *et al.*

No. 31

Screening for hepatitis C among injecting drug users and in genitourinary medicine clinics: systematic reviews of effectiveness, modelling study and national survey of current practice.

By Stein K, Dalziel K, Walker A, McIntyre L, Jenkins B, Horne J, *et al.*

No. 32

The measurement of satisfaction with healthcare: implications for practice from a systematic review of the literature.

By Crow R, Gage H, Hampson S, Hart J, Kimber A, Storey L, *et al.*

No. 33

The effectiveness and cost-effectiveness of imatinib in chronic myeloid leukaemia: a systematic review.

By Garside R, Round A, Dalziel K, Stein K, Royle R.

No. 34

A comparative study of hypertonic saline, daily and alternate-day rhDNase in children with cystic fibrosis.

By Suri R, Wallis C, Bush A, Thompson S, Normand C, Flather M, *et al.*

No. 35

A systematic review of the costs and effectiveness of different models of paediatric home care.

By Parker G, Bhakta P, Lovett CA, Paisley S, Olsen R, Turner D, *et al.*

Volume 7, 2003

No. 1

How important are comprehensive literature searches and the assessment of trial quality in systematic reviews? Empirical study.

By Egger M, Jüni P, Bartlett C, Holenstein F, Sterne J.

No. 2

Systematic review of the effectiveness and cost-effectiveness, and economic evaluation, of home versus hospital or satellite unit haemodialysis for people with end-stage renal failure.

By Mowatt G, Vale L, Perez J, Wyness L, Fraser C, MacLeod A, *et al.*

No. 3

Systematic review and economic evaluation of the effectiveness of infliximab for the treatment of Crohn's disease.

By Clark W, Raftery J, Barton P, Song F, Fry-Smith A, Burls A.

No. 4

A review of the clinical effectiveness and cost-effectiveness of routine anti-D prophylaxis for pregnant women who are rhesus negative.

By Chilcott J, Lloyd Jones M, Wight J, Forman K, Wray J, Beverley C, *et al.*

No. 5

Systematic review and evaluation of the use of tumour markers in paediatric oncology: Ewing's sarcoma and neuroblastoma.

By Riley RD, Burchill SA, Abrams KR, Heney D, Lambert PC, Jones DR, *et al.*

No. 6

The cost-effectiveness of screening for *Helicobacter pylori* to reduce mortality and morbidity from gastric cancer and peptic ulcer disease: a discrete-event simulation model.

By Roderick P, Davies R, Raftery J, Crabbe D, Pearce R, Bhandari P, *et al.*

No. 7

The clinical effectiveness and cost-effectiveness of routine dental checks: a systematic review and economic evaluation.

By Davenport C, Elley K, Salas C, Taylor-Weetman CL, Fry-Smith A, Bryan S, *et al.*

No. 8

A multicentre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia.

By Kennedy ADM, Sculpher MJ, Coulter A, Dwyer N, Rees M, Horsley S, *et al.*

No. 9

Clinical effectiveness and cost-utility of photodynamic therapy for wet age-related macular degeneration: a systematic review and economic evaluation.

By Meads C, Salas C, Roberts T, Moore D, Fry-Smith A, Hyde C.

No. 10

Evaluation of molecular tests for prenatal diagnosis of chromosome abnormalities.

By Grimshaw GM, Szczepura A, Hultén M, MacDonald F, Nevin NC, Sutton F, *et al.*

No. 11

First and second trimester antenatal screening for Down's syndrome: the results of the Serum, Urine and Ultrasound Screening Study (SURUSS).

By Wald NJ, Rodeck C, Hackshaw AK, Walters J, Chitty L, Mackinson AM.

No. 12

The effectiveness and cost-effectiveness of ultrasound locating devices for central venous access: a systematic review and economic evaluation.

By Calvert N, Hind D, McWilliams RG, Thomas SM, Beverley C, Davidson A.

No. 13

A systematic review of atypical antipsychotics in schizophrenia.

By Bagnall A-M, Jones L, Lewis R, Ginnelly L, Glanville J, Torgerson D, *et al.*

No. 14

Prostate Testing for Cancer and Treatment (ProtecT) feasibility study.

By Donovan J, Hamdy F, Neal D, Peters T, Oliver S, Brindle L, *et al.*

No. 15

Early thrombolysis for the treatment of acute myocardial infarction: a systematic review and economic evaluation.

By Boland A, Dundar Y, Bagust A, Haycox A, Hill R, Mujica Mota R, *et al.*

No. 16

Screening for fragile X syndrome: a literature review and modelling.

By Song FJ, Barton P, Sleightholme V, Yao GL, Fry-Smith A.

No. 17

Systematic review of endoscopic sinus surgery for nasal polyps.

By Dalziel K, Stein K, Round A, Garside R, Royle P.

No. 18

Towards efficient guidelines: how to monitor guideline use in primary care.

By Hutchinson A, McIntosh A, Cox S, Gilbert C.

No. 19

Effectiveness and cost-effectiveness of acute hospital-based spinal cord injuries services: systematic review.

By Bagnall A-M, Jones L, Richardson G, Duffy S, Riemsma R.

No. 20

Prioritisation of health technology assessment. The PATHS model: methods and case studies.

By Townsend J, Buxton M, Harper G.

No. 21

Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence.

By Cody J, Wyness L, Wallace S, Glazener C, Kilonzo M, Stearns S, *et al.*

No. 22

The clinical and cost-effectiveness of patient education models for diabetes: a systematic review and economic evaluation.

By Loveman E, Cave C, Green C, Royle P, Dunn N, Waugh N.

No. 23

The role of modelling in prioritising and planning clinical trials.

By Chilcott J, Brennan A, Booth A, Karnon J, Tappenden P.

No. 24

Cost-benefit evaluation of routine influenza immunisation in people 65-74 years of age.

By Allsup S, Gosney M, Haycox A, Regan M.

No. 25

The clinical and cost-effectiveness of pulsatile machine perfusion versus cold storage of kidneys for transplantation retrieved from heart-beating and non-heart-beating donors.

By Wight J, Chilcott J, Holmes M, Brewer N.

No. 26

Can randomised trials rely on existing electronic data? A feasibility study to explore the value of routine data in health technology assessment.

By Williams JG, Cheung WY, Cohen DR, Hutchings HA, Longo MF, Russell IT.

No. 27

Evaluating non-randomised intervention studies.

By Deeks JJ, Dinnes J, D'Amico R, Sowden AJ, Sakarovich C, Song F, *et al.*

No. 28

A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease.

By Kennedy A, Nelson E, Reeves D, Richardson G, Roberts C, Robinson A, *et al.*

No. 29

The effectiveness of diagnostic tests for the assessment of shoulder pain due to soft tissue disorders: a systematic review.

By Dinnes J, Loveman E, McIntyre L, Waugh N.

No. 30

The value of digital imaging in diabetic retinopathy.

By Sharp PE, Olson J, Strachan F, Hipwell J, Ludbrook A, O'Donnell M, *et al.*

No. 31

Lowering blood pressure to prevent myocardial infarction and stroke: a new preventive strategy.

By Law M, Wald N, Morris J.

No. 32

Clinical and cost-effectiveness of capecitabine and tegafur with uracil for the treatment of metastatic colorectal cancer: systematic review and economic evaluation.

By Ward S, Kaltenthaler E, Cowan J, Brewer N.

No. 33

Clinical and cost-effectiveness of new and emerging technologies for early localised prostate cancer: a systematic review.

By Hummel S, Paisley S, Morgan A, Currie E, Brewer N.

No. 34

Literature searching for clinical and cost-effectiveness studies used in health technology assessment reports carried out for the National Institute for Clinical Excellence appraisal system.

By Royle P, Waugh N.

No. 35

Systematic review and economic decision modelling for the prevention and treatment of influenza A and B.

By Turner D, Wailoo A, Nicholson K, Cooper N, Sutton A, Abrams K.

No. 36

A randomised controlled trial to evaluate the clinical and cost-effectiveness of Hickman line insertions in adult cancer patients by nurses.

By Boland A, Haycox A, Bagust A, Fitzsimmons L.

No. 37

Redesigning postnatal care: a randomised controlled trial of protocol-based midwifery-led care focused on individual women's physical and psychological health needs.

By MacArthur C, Winter HR, Bick DE, Lilford RJ, Lancashire RJ, Knowles H, *et al.*

No. 38

Estimating implied rates of discount in healthcare decision-making.

By West RR, McNabb R, Thompson AGH, Sheldon TA, Grimley Evans J.

No. 39

Systematic review of isolation policies in the hospital management of methicillin-resistant *Staphylococcus aureus*: a review of the literature with epidemiological and economic modelling.

By Cooper BS, Stone SP, Kibbler CC, Cookson BD, Roberts JA, Medley GF, *et al.*

No. 40

Treatments for spasticity and pain in multiple sclerosis: a systematic review.

By Beard S, Hunn A, Wight J.

No. 41

The inclusion of reports of randomised trials published in languages other than English in systematic reviews.

By Moher D, Pham B, Lawson ML, Klassen TP.

No. 42

The impact of screening on future health-promoting behaviours and health beliefs: a systematic review.

By Bankhead CR, Brett J, Bukach C, Webster P, Stewart-Brown S, Munafa M, *et al.*

Volume 8, 2004

No. 1

What is the best imaging strategy for acute stroke?

By Wardlaw JM, Keir SL, Seymour J, Lewis S, Sandercock PAG, Dennis MS, *et al.*

No. 2

Systematic review and modelling of the investigation of acute and chronic chest pain presenting in primary care.

By Mant J, McManus RJ, Oakes RAL, Delaney BC, Barton PM, Deeks JJ, *et al.*

No. 3

The effectiveness and cost-effectiveness of microwave and thermal balloon endometrial ablation for heavy menstrual bleeding: a systematic review and economic modelling.

By Garside R, Stein K, Wyatt K, Round A, Price A.

No. 4

A systematic review of the role of bisphosphonates in metastatic disease.

By Ross JR, Saunders Y, Edmonds PM, Patel S, Wonderling D, Normand C, *et al.*

No. 5

Systematic review of the clinical effectiveness and cost-effectiveness of capecitabine (Xeloda®) for locally advanced and/or metastatic breast cancer.

By Jones L, Hawkins N, Westwood M, Wright K, Richardson G, Riemsma R.

No. 6

Effectiveness and efficiency of guideline dissemination and implementation strategies.

By Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, *et al.*

No. 7

Clinical effectiveness and costs of the Sugarbaker procedure for the treatment of pseudomyxoma peritonei.

By Bryant J, Clegg AJ, Sidhu MK, Brodin H, Royle P, Davidson P.

No. 8

Psychological treatment for insomnia in the regulation of long-term hypnotic drug use.

By Morgan K, Dixon S, Mathers N, Thompson J, Tomeny M.

No. 9

Improving the evaluation of therapeutic interventions in multiple sclerosis: development of a patient-based measure of outcome.

By Hobart JC, Riazi A, Lamping DL, Fitzpatrick R, Thompson AJ.

No. 10

A systematic review and economic evaluation of magnetic resonance cholangiopancreatography compared with diagnostic endoscopic retrograde cholangiopancreatography.

By Kaltenthaler E, Bravo Vergel Y, Chilcott J, Thomas S, Blakeborough T, Walters SJ, *et al.*

No. 11

The use of modelling to evaluate new drugs for patients with a chronic condition: the case of antibodies against tumour necrosis factor in rheumatoid arthritis.

By Barton P, Jobanputra P, Wilson J, Bryan S, Burls A.

No. 12

Clinical effectiveness and cost-effectiveness of neonatal screening for inborn errors of metabolism using tandem mass spectrometry: a systematic review.

By Pandor A, Eastham J, Beverley C, Chilcott J, Paisley S.

No. 13

Clinical effectiveness and cost-effectiveness of pioglitazone and rosiglitazone in the treatment of type 2 diabetes: a systematic review and economic evaluation.

By Czoski-Murray C, Warren E, Chilcott J, Beverley C, Psyllaki MA, Cowan J.

No. 14

Routine examination of the newborn: the EMREN study. Evaluation of an extension of the midwife role including a randomised controlled trial of appropriately trained midwives and paediatric senior house officers.

By Townsend J, Wolke D, Hayes J, Davé S, Rogers C, Bloomfield L, *et al.*

No. 15

Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach.

By Oliver S, Clarke-Jones L, Rees R, Milne R, Buchanan P, Gabbay J, *et al.*

No. 16

A multi-centre randomised controlled trial of minimally invasive direct coronary bypass grafting versus percutaneous transluminal coronary angioplasty with stenting for proximal stenosis of the left anterior descending coronary artery.

By Reeves BC, Angelini GD, Bryan AJ, Taylor FC, Cripps T, Spyt TJ, *et al.*

No. 17

Does early magnetic resonance imaging influence management or improve outcome in patients referred to secondary care with low back pain? A pragmatic randomised controlled trial.

By Gilbert FJ, Grant AM, Gillan MGC, Vale L, Scott NW, Campbell MK, *et al.*

No. 18

The clinical and cost-effectiveness of anakinra for the treatment of rheumatoid arthritis in adults: a systematic review and economic analysis.

By Clark W, Jobanputra P, Barton P, Burls A.

No. 19

A rapid and systematic review and economic evaluation of the clinical and cost-effectiveness of newer drugs for treatment of mania associated with bipolar affective disorder.

By Bridle C, Palmer S, Bagnall A-M, Darba J, Duffy S, Sculpher M, *et al.*

No. 20

Liquid-based cytology in cervical screening: an updated rapid and systematic review and economic analysis.

By Karnon J, Peters J, Platt J, Chilcott J, McGoogan E, Brewer N.

No. 21

Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement.

By Avenell A, Broom J, Brown TJ, Poobalan A, Aucott L, Stearns SC, *et al.*

No. 22

Autoantibody testing in children with newly diagnosed type 1 diabetes mellitus.

By Dretzke J, Cummins C, Sandercock J, Fry-Smith A, Barrett T, Burls A.

No. 23

Clinical effectiveness and cost-effectiveness of prehospital intravenous fluids in trauma patients.

By Dretzke J, Sandercock J, Bayliss S, Burls A.

No. 24

Newer hypnotic drugs for the short-term management of insomnia: a systematic review and economic evaluation.

By Dündar Y, Boland A, Strobl J, Dodd S, Haycox A, Bagust A, *et al.*

No. 25

Development and validation of methods for assessing the quality of diagnostic accuracy studies.

By Whiting P, Rutjes AWS, Dinnes J, Reitsma JB, Bossuyt PMM, Kleijnen J.

No. 26

EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy.

By Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M, *et al.*

No. 27

Methods for expected value of information analysis in complex health economic models: developments on the health economics of interferon- β and glatiramer acetate for multiple sclerosis.

By Tappenden P, Chilcott JB, Eggington S, Oakley J, McCabe C.

No. 28

Effectiveness and cost-effectiveness of imatinib for first-line treatment of chronic myeloid leukaemia in chronic phase: a systematic review and economic analysis.

By Dalziel K, Round A, Stein K, Garside R, Price A.

No. 29

VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers.

By Iglesias C, Nelson EA, Cullum NA, Torgerson DJ on behalf of the VenUS Team.

No. 30

Systematic review of the effectiveness and cost-effectiveness, and economic evaluation, of myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction.

By Mowatt G, Vale L, Brazzelli M, Hernandez R, Murray A, Scott N, *et al.*

No. 31

A pilot study on the use of decision theory and value of information analysis as part of the NHS Health Technology Assessment programme.

By Claxton K, Ginnelly L, Sculpher M, Philips Z, Palmer S.

No. 32

The Social Support and Family Health Study: a randomised controlled trial and economic evaluation of two alternative forms of postnatal support for mothers living in disadvantaged inner-city areas.

By Wiggins M, Oakley A, Roberts I, Turner H, Rajan L, Austerberry H, *et al.*

No. 33

Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review.

By Green JM, Hewison J, Bekker HL, Bryant, Cuckle HS.

No. 34

Evaluation of abnormal uterine bleeding: comparison of three outpatient procedures within cohorts defined by age and menopausal status.

By Critchley HOD, Warner P, Lee AJ, Brechin S, Guise J, Graham B.

No. 35

Coronary artery stents: a rapid systematic review and economic evaluation.

By Hill R, Bagust A, Bakhai A, Dickson R, Dündar Y, Haycox A, *et al.*

No. 36

Review of guidelines for good practice in decision-analytic modelling in health technology assessment.

By Philips Z, Ginnelly L, Sculpher M, Claxton K, Golder S, Riemsma R, *et al.*

No. 37

Rituximab (MabThera[®]) for aggressive non-Hodgkin's lymphoma: systematic review and economic evaluation.

By Knight C, Hind D, Brewer N, Abbott V.

No. 38

Clinical effectiveness and cost-effectiveness of clopidogrel and modified-release dipyridamole in the secondary prevention of occlusive vascular events: a systematic review and economic evaluation.

By Jones L, Griffin S, Palmer S, Main C, Orton V, Sculpher M, *et al.*

No. 39

Pegylated interferon α -2a and -2b in combination with ribavirin in the treatment of chronic hepatitis C: a systematic review and economic evaluation.

By Shepherd J, Brodin H, Cave C, Waugh N, Price A, Gabbay J.

No. 40

Clopidogrel used in combination with aspirin compared with aspirin alone in the treatment of non-ST-segment-elevation acute coronary syndromes: a systematic review and economic evaluation.

By Main C, Palmer S, Griffin S, Jones L, Orton V, Sculpher M, *et al.*

No. 41

Provision, uptake and cost of cardiac rehabilitation programmes: improving services to under-represented groups.

By Beswick AD, Rees K, Griebisch I, Taylor FC, Burke M, West RR, *et al.*

No. 42

Involving South Asian patients in clinical trials.

By Hussain-Gambles M, Leese B, Atkin K, Brown J, Mason S, Tovey P.

No. 43

Clinical and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes.

By Colquitt JL, Green C, Sidhu MK, Hartwell D, Waugh N.

No. 44

Identification and assessment of ongoing trials in health technology assessment reviews.

By Song FJ, Fry-Smith A, Davenport C, Bayliss S, Adi Y, Wilson JS, *et al.*

No. 45

Systematic review and economic evaluation of a long-acting insulin analogue, insulin glargine

By Warren E, Weatherley-Jones E, Chilcott J, Beverley C.

No. 46

Supplementation of a home-based exercise programme with a class-based programme for people with osteoarthritis of the knees: a randomised controlled trial and health economic analysis.

By McCarthy CJ, Mills PM, Pullen R, Richardson G, Hawkins N, Roberts CR, *et al.*

No. 47

Clinical and cost-effectiveness of once-daily versus more frequent use of same potency topical corticosteroids for atopic eczema: a systematic review and economic evaluation.

By Green C, Colquitt JL, Kirby J, Davidson P, Payne E.

No. 48

Acupuncture of chronic headache disorders in primary care: randomised controlled trial and economic analysis.

By Vickers AJ, Rees RW, Zollman CE, McCarney R, Smith CM, Ellis N, *et al.*

No. 49

Generalisability in economic evaluation studies in healthcare: a review and case studies.

By Sculpher MJ, Pang FS, Manca A, Drummond MF, Golder S, Urdahl H, *et al.*

No. 50

Virtual outreach: a randomised controlled trial and economic evaluation of joint teleconferenced medical consultations.

By Wallace P, Barber J, Clayton W, Currell R, Fleming K, Garner P, *et al.*

Volume 9, 2005

No. 1

Randomised controlled multiple treatment comparison to provide a cost-effectiveness rationale for the selection of antimicrobial therapy in acne.

By Ozolins M, Eady EA, Avery A, Cunliffe WJ, O'Neill C, Simpson NB, *et al.*

No. 2

Do the findings of case series studies vary significantly according to methodological characteristics?

By Dalziel K, Round A, Stein K, Garside R, Castelnovo E, Payne L.

No. 3

Improving the referral process for familial breast cancer genetic counselling: findings of three randomised controlled trials of two interventions.

By Wilson BJ, Torrance N, Mollison J, Wordsworth S, Gray JR, Haites NE, *et al.*

No. 4

Randomised evaluation of alternative electrosurgical modalities to treat bladder outflow obstruction in men with benign prostatic hyperplasia.

By Fowler C, McAllister W, Plail R, Karim O, Yang Q.

No. 5

A pragmatic randomised controlled trial of the cost-effectiveness of palliative therapies for patients with inoperable oesophageal cancer.

By Shenfine J, McNamee P, Steen N, Bond J, Griffin SM.

No. 6

Impact of computer-aided detection prompts on the sensitivity and specificity of screening mammography.

By Taylor P, Champness J, Given-Wilson R, Johnston K, Potts H.

No. 7

Issues in data monitoring and interim analysis of trials.

By Grant AM, Altman DG, Babiker AB, Campbell MK, Clemens FJ, Darbyshire JH, *et al.*

No. 8

Lay public's understanding of equipoise and randomisation in randomised controlled trials.

By Robinson EJ, Kerr CEP, Stevens AJ, Lilford RJ, Brauholtz DA, Edwards SJ, *et al.*

No. 9

Clinical and cost-effectiveness of electroconvulsive therapy for depressive illness, schizophrenia, catatonia and mania: systematic reviews and economic modelling studies.

By Greenhalgh J, Knight C, Hind D, Beverley C, Walters S.

No. 10

Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology.

By Smith SC, Lamping DL, Banerjee S, Harwood R, Foley B, Smith P, *et al.*

No. 11

Clinical effectiveness and cost-effectiveness of drotrecogin alfa (activated) (Xigris®) for the treatment of severe sepsis in adults: a systematic review and economic evaluation.

By Green C, Dinnes J, Takeda A, Shepherd J, Hartwell D, Cave C, *et al.*

No. 12

A methodological review of how heterogeneity has been examined in systematic reviews of diagnostic test accuracy.

By Dinnes J, Deeks J, Kirby J, Roderick P.

No. 13

Cervical screening programmes: can automation help? Evidence from systematic reviews, an economic analysis and a simulation modelling exercise applied to the UK.

By Willis BH, Barton P, Pearmain P, Bryan S, Hyde C.

No. 14

Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation.

By McCormack K, Wake B, Perez J, Fraser C, Cook J, McIntosh E, *et al.*

No. 15

Clinical effectiveness, tolerability and cost-effectiveness of newer drugs for epilepsy in adults: a systematic review and economic evaluation.

By Wilby J, Kainth A, Hawkins N, Epstein D, McIntosh H, McDaid C, *et al.*

No. 16

A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin reuptake inhibitors and lofepramine.

By Peveler R, Kendrick T, Buxton M, Longworth L, Baldwin D, Moore M, *et al.*

No. 17

Clinical effectiveness and cost-effectiveness of immediate angioplasty for acute myocardial infarction: systematic review and economic evaluation.

By Hartwell D, Colquitt J, Loveman E, Clegg AJ, Brodin H, Waugh N, *et al.*

No. 18

A randomised controlled comparison of alternative strategies in stroke care.

By Kalra L, Evans A, Perez I, Knapp M, Swift C, Donaldson N.

No. 19

The investigation and analysis of critical incidents and adverse events in healthcare.

By Woloshnowych M, Rogers S, Taylor-Adams S, Vincent C.

No. 20

Potential use of routine databases in health technology assessment.

By Raftery J, Roderick P, Stevens A.

No. 21

Clinical and cost-effectiveness of newer immunosuppressive regimens in renal transplantation: a systematic review and modelling study.

By Woodroffe R, Yao GL, Meads C, Bayliss S, Ready A, Raftery J, *et al.*

No. 22

A systematic review and economic evaluation of alendronate, etidronate, risedronate, raloxifene and teriparatide for the prevention and treatment of postmenopausal osteoporosis.

By Stevenson M, Lloyd Jones M, De Nigris E, Brewer N, Davis S, Oakley J.

No. 23

A systematic review to examine the impact of psycho-educational interventions on health outcomes and costs in adults and children with difficult asthma.

By Smith JR, Mugford M, Holland R, Candy B, Noble MJ, Harrison BDW, *et al.*

No. 24

An evaluation of the costs, effectiveness and quality of renal replacement therapy provision in renal satellite units in England and Wales.

By Roderick P, Nicholson T, Armitage A, Mehta R, Mullee M, Gerard K, *et al.*

No. 25

Imatinib for the treatment of patients with unresectable and/or metastatic gastrointestinal stromal tumours: systematic review and economic evaluation.

By Wilson J, Connock M, Song F, Yao G, Fry-Smith A, Raftery J, *et al.*

No. 26

Indirect comparisons of competing interventions.

By Glenny AM, Altman DG, Song F, Sakarovich C, Deeks JJ, D'Amico R, *et al.*

No. 27

Cost-effectiveness of alternative strategies for the initial medical management of non-ST elevation acute coronary syndrome: systematic review and decision-analytical modelling.

By Robinson M, Palmer S, Sculpher M, Philips Z, Ginnelly L, Bowens A, *et al.*

No. 28

Outcomes of electrically stimulated gracilis neosphincter surgery.

By Tillin T, Chambers M, Feldman R.

No. 29

The effectiveness and cost-effectiveness of pimecrolimus and tacrolimus for atopic eczema: a systematic review and economic evaluation.

By Garside R, Stein K, Castelnovo E, Pitt M, Ashcroft D, Dimmock P, *et al.*

No. 30

Systematic review on urine albumin testing for early detection of diabetic complications.

By Newman DJ, Mattock MB, Dawney ABS, Kerry S, McGuire A, Yaqoob M, *et al.*

No. 31

Randomised controlled trial of the cost-effectiveness of water-based therapy for lower limb osteoarthritis.

By Cochrane T, Davey RC, Matthes Edwards SM.

No. 32

Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain.

By Thomas KJ, MacPherson H, Ratcliffe J, Thorpe L, Brazier J, Campbell M, *et al.*

No. 33

Cost-effectiveness and safety of epidural steroids in the management of sciatica.

By Price C, Arden N, Cogan L, Rogers P.

No. 34

The British Rheumatoid Outcome Study Group (BROSG) randomised controlled trial to compare the effectiveness and cost-effectiveness of aggressive versus symptomatic therapy in established rheumatoid arthritis.

By Symmons D, Tricker K, Roberts C, Davies L, Dawes P, Scott DL.

No. 35

Conceptual framework and systematic review of the effects of participants' and professionals' preferences in randomised controlled trials.

By King M, Nazareth I, Lampe F, Bower P, Chandler M, Morou M, *et al.*

No. 36

The clinical and cost-effectiveness of implantable cardioverter defibrillators: a systematic review.

By Bryant J, Brodin H, Loveman E, Payne E, Clegg A.

No. 37

A trial of problem-solving by community mental health nurses for anxiety, depression and life difficulties among general practice patients. The CPN-GP study.

By Kendrick T, Simons L, Mynors-Wallis L, Gray A, Lathlean J, Pickering R, *et al.*

No. 38

The causes and effects of socio-demographic exclusions from clinical trials.

By Bartlett C, Doyal L, Ebrahim S, Davey P, Bachmann M, Egger M, *et al.*

No. 39

Is hydrotherapy cost-effective? A randomised controlled trial of combined hydrotherapy programmes compared with physiotherapy land techniques in children with juvenile idiopathic arthritis.

By Epps H, Ginnelly L, Utley M, Southwood T, Gallivan S, Sculpher M, *et al.*

No. 40

A randomised controlled trial and cost-effectiveness study of systematic screening (targeted and total population screening) versus routine practice for the detection of atrial fibrillation in people aged 65 and over. The SAFE study.

By Hobbs FDR, Fitzmaurice DA, Mant J, Murray E, Jowett S, Bryan S, *et al.*

No. 41

Displaced intracapsular hip fractures in fit, older people: a randomised comparison of reduction and fixation, bipolar hemiarthroplasty and total hip arthroplasty.

By Keating JF, Grant A, Masson M, Scott NW, Forbes JF.

No. 42

Long-term outcome of cognitive behaviour therapy clinical trials in central Scotland.

By Durham RC, Chambers JA, Power KG, Sharp DM, Macdonald RR, Major KA, *et al.*

No. 43

The effectiveness and cost-effectiveness of dual-chamber pacemakers compared with single-chamber pacemakers for bradycardia due to atrioventricular block or sick sinus syndrome: systematic review and economic evaluation.

By Castelnovo E, Stein K, Pitt M, Garside R, Payne E.

No. 44

Newborn screening for congenital heart defects: a systematic review and cost-effectiveness analysis.

By Knowles R, Griebsch I, Dezateux C, Brown J, Bull C, Wren C.

No. 45

The clinical and cost-effectiveness of left ventricular assist devices for end-stage heart failure: a systematic review and economic evaluation.

By Clegg AJ, Scott DA, Loveman E, Colquitt J, Hutchinson J, Royle P, *et al.*

No. 46

The effectiveness of the Heidelberg Retina Tomograph and laser diagnostic glaucoma scanning system (GDx) in detecting and monitoring glaucoma.

By Kwartz AJ, Henson DB, Harper RA, Spencer AF, McLeod D.

No. 47

Clinical and cost-effectiveness of autologous chondrocyte implantation for cartilage defects in knee joints: systematic review and economic evaluation.

By Clar C, Cummins E, McIntyre L, Thomas S, Lamb J, Bain L, *et al.*

No. 48

Systematic review of effectiveness of different treatments for childhood retinoblastoma.

By McDaid C, Hartley S, Bagnall A-M, Ritchie G, Light K, Riemsma R.

No. 49

Towards evidence-based guidelines for the prevention of venous thromboembolism: systematic reviews of mechanical methods, oral anticoagulation, dextran and regional anaesthesia as thromboprophylaxis.

By Roderick P, Ferris G, Wilson K, Halls H, Jackson D, Collins R, *et al.*

No. 50

The effectiveness and cost-effectiveness of parent training/education programmes for the treatment of conduct disorder, including oppositional defiant disorder, in children.

By Dretzke J, Frew E, Davenport C, Barlow J, Stewart-Brown S, Sandercock J, *et al.*

Volume 10, 2006**No. 1**

The clinical and cost-effectiveness of donepezil, rivastigmine, galantamine and memantine for Alzheimer's disease.

By Loveman E, Green C, Kirby J, Takeda A, Picot J, Payne E, *et al.*

No. 2

FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke.

By Dennis M, Lewis S, Cranswick G, Forbes J.

No. 3

The clinical effectiveness and cost-effectiveness of computed tomography screening for lung cancer: systematic reviews.

By Black C, Bagust A, Boland A, Walker S, McLeod C, De Verteuil R, *et al.*

No. 4

A systematic review of the effectiveness and cost-effectiveness of neuroimaging assessments used to visualise the seizure focus in people with refractory epilepsy being considered for surgery.

By Whiting P, Gupta R, Burch J, Mujica Mota RE, Wright K, Marson A, *et al.*

No. 5

Comparison of conference abstracts and presentations with full-text articles in the health technology assessments of rapidly evolving technologies.

By Dundar Y, Dodd S, Dickson R, Walley T, Haycox A, Williamson PR.

No. 6

Systematic review and evaluation of methods of assessing urinary incontinence.

By Martin JL, Williams KS, Abrams KR, Turner DA, Sutton AJ, Chapple C, *et al.*

No. 7

The clinical effectiveness and cost-effectiveness of newer drugs for children with epilepsy. A systematic review.

By Connock M, Frew E, Evans B-W, Bryan S, Cummins C, Fry-Smith A, *et al.*

No. 8

Surveillance of Barrett's oesophagus: exploring the uncertainty through systematic review, expert workshop and economic modelling.

By Garside R, Pitt M, Somerville M, Stein K, Price A, Gilbert N.

No. 9

Topotecan, pegylated liposomal doxorubicin hydrochloride and paclitaxel for second-line or subsequent treatment of advanced ovarian cancer: a systematic review and economic evaluation.

By Main C, Bojke L, Griffin S, Norman G, Barbieri M, Mather L, *et al.*

No. 10

Evaluation of molecular techniques in prediction and diagnosis of cytomegalovirus disease in immunocompromised patients.

By Szczepura A, Westmoreland D, Vinogradova Y, Fox J, Clark M.

No. 11

Screening for thrombophilia in high-risk situations: systematic review and cost-effectiveness analysis. The Thrombosis: Risk and Economic Assessment of Thrombophilia Screening (TREATS) study.

By Wu O, Robertson L, Twaddle S, Lowe GDO, Clark P, Greaves M, *et al.*

No. 12

A series of systematic reviews to inform a decision analysis for sampling and treating infected diabetic foot ulcers.

By Nelson EA, O'Meara S, Craig D, Iglesias C, Golder S, Dalton J, *et al.*

No. 13

Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial).

By Michaels JA, Campbell WB, Brazier JE, MacIntyre JB, Palfreyman SJ, Ratcliffe J, *et al.*

No. 14

The cost-effectiveness of screening for oral cancer in primary care.

By Speight PM, Palmer S, Moles DR, Downer MC, Smith DH, Henriksson M *et al.*

No. 15

Measurement of the clinical and cost-effectiveness of non-invasive diagnostic testing strategies for deep vein thrombosis.

By Goodacre S, Sampson F, Stevenson M, Wailoo A, Sutton A, Thomas S, *et al.*

No. 16

Systematic review of the effectiveness and cost-effectiveness of HealOzone[®] for the treatment of occlusal pit/fissure caries and root caries.

By Brazzelli M, McKenzie L, Fielding S, Fraser C, Clarkson J, Kilonzo M, *et al.*

No. 17

Randomised controlled trials of conventional antipsychotic versus new atypical drugs, and new atypical drugs versus clozapine, in people with schizophrenia responding poorly to, or intolerant of, current drug treatment.

By Lewis SW, Davies L, Jones PB, Barnes TRE, Murray RM, Kerwin R, *et al.*

No. 18

Diagnostic tests and algorithms used in the investigation of haematuria: systematic reviews and economic evaluation.

By Rodgers M, Nixon J, Hempel S, Aho T, Kelly J, Neal D, *et al.*

No. 19

Cognitive behavioural therapy in addition to antispasmodic therapy for irritable bowel syndrome in primary care: randomised controlled trial.

By Kennedy TM, Chalder T, McCrone P, Darnley S, Knapp M, Jones RH, *et al.*

No. 20

A systematic review of the clinical effectiveness and cost-effectiveness of enzyme replacement therapies for Fabry's disease and mucopolysaccharidosis type 1.

By Connock M, Juarez-Garcia A, Frew E, Mans A, Dretzke J, Fry-Smith A, *et al.*

No. 21

Health benefits of antiviral therapy for mild chronic hepatitis C: randomised controlled trial and economic evaluation.

By Wright M, Grieve R, Roberts J, Main J, Thomas HC on behalf of the UK Mild Hepatitis C Trial Investigators.

No. 22

Pressure relieving support surfaces: a randomised evaluation.

By Nixon J, Nelson EA, Cranny G, Iglesias CP, Hawkins K, Cullum NA, *et al.*

No. 23

A systematic review and economic model of the effectiveness and cost-effectiveness of methylphenidate, dexamfetamine and atomoxetine for the treatment of attention deficit hyperactivity disorder in children and adolescents.

By King S, Griffin S, Hodges Z, Weatherly H, Asseburg C, Richardson G, *et al.*

No. 24

The clinical effectiveness and cost-effectiveness of enzyme replacement therapy for Gaucher's disease: a systematic review.

By Connock M, Burls A, Frew E, Fry-Smith A, Juarez-Garcia A, McCabe C, *et al.*

No. 25

Effectiveness and cost-effectiveness of salicylic acid and cryotherapy for cutaneous warts. An economic decision model.

By Thomas KS, Keogh-Brown MR, Chalmers JR, Fordham RJ, Holland RC, Armstrong SJ, *et al.*

No. 26

A systematic literature review of the effectiveness of non-pharmacological interventions to prevent wandering in dementia and evaluation of the ethical implications and acceptability of their use.

By Robinson L, Hutchings D, Corner L, Beyer F, Dickinson H, Vanoli A, *et al.*

No. 27

A review of the evidence on the effects and costs of implantable cardioverter defibrillator therapy in different patient groups, and modelling of cost-effectiveness and cost-utility for these groups in a UK context.

By Buxton M, Caine N, Chase D, Connelly D, Grace A, Jackson C, *et al.*

No. 28

Adefovir dipivoxil and pegylated interferon alfa-2a for the treatment of chronic hepatitis B: a systematic review and economic evaluation.

By Shepherd J, Jones J, Takeda A, Davidson P, Price A.

No. 29

An evaluation of the clinical and cost-effectiveness of pulmonary artery catheters in patient management in intensive care: a systematic review and a randomised controlled trial.

By Harvey S, Stevens K, Harrison D, Young D, Brampton W, McCabe C, *et al.*

No. 30

Accurate, practical and cost-effective assessment of carotid stenosis in the UK.

By Wardlaw JM, Chappell FM, Stevenson M, De Nigris E, Thomas S, Gillard J, *et al.*

No. 31

Etanercept and infliximab for the treatment of psoriatic arthritis: a systematic review and economic evaluation.

By Woolacott N, Bravo Vergel Y, Hawkins N, Kainth A, Khadjesari Z, Misso K, *et al.*

No. 32

The cost-effectiveness of testing for hepatitis C in former injecting drug users.

By Castelnuovo E, Thompson-Coon J, Pitt M, Cramp M, Siebert U, Price A, *et al.*

No. 33

Computerised cognitive behaviour therapy for depression and anxiety update: a systematic review and economic evaluation.

By Kaltenthaler E, Brazier J, De Nigris E, Tumor I, Ferriter M, Beverley C, *et al.*

No. 34

Cost-effectiveness of using prognostic information to select women with breast cancer for adjuvant systemic therapy.

By Williams C, Brunskill S, Altman D, Briggs A, Campbell H, Clarke M, *et al.*

No. 35

Psychological therapies including dialectical behaviour therapy for borderline personality disorder: a systematic review and preliminary economic evaluation.

By Brazier J, Tumor I, Holmes M, Ferriter M, Parry G, Dent-Brown K, *et al.*

No. 36

Clinical effectiveness and cost-effectiveness of tests for the diagnosis and investigation of urinary tract infection in children: a systematic review and economic model.

By Whiting P, Westwood M, Bojke L, Palmer S, Richardson G, Cooper J, *et al.*

No. 37

Cognitive behavioural therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme.

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A comparison of the cost-effectiveness of five strategies for the prevention of non-steroidal anti-inflammatory drug-induced gastrointestinal toxicity: a systematic review with economic modelling.

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The effectiveness and cost-effectiveness of computed tomography screening for coronary artery disease: systematic review.

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What are the clinical outcome and cost-effectiveness of endoscopy undertaken by nurses when compared with doctors? A Multi-Institution Nurse Endoscopy Trial (MINuET).

By Williams J, Russell I, Durai D, Cheung WY, Farrin A, Bloor K, *et al.*

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The clinical and cost-effectiveness of oxaliplatin and capecitabine for the adjuvant treatment of colon cancer: systematic review and economic evaluation.

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By Murray A, Lourenco T, de Verteuil R, Hernandez R, Fraser C, McKinlay A, *et al.*

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Etanercept and efalizumab for the treatment of psoriasis: a systematic review.

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Systematic reviews of clinical decision tools for acute abdominal pain.

By Liu JLY, Wyatt JC, Deeks JJ, Clamp S, Keen J, Verde P, *et al.*

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Volume 11, 2007**No. 1**

Pemetrexed disodium for the treatment of malignant pleural mesothelioma: a systematic review and economic evaluation.

By Dundar Y, Bagust A, Dickson R, Dodd S, Green J, Haycox A, *et al.*

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Exercise Evaluation Randomised Trial (EXERT): a randomised trial comparing GP referral for leisure centre-based exercise, community-based walking and advice only.

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Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of mild chronic hepatitis C: a systematic review and economic evaluation.

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Systematic review and economic evaluation of bevacizumab and cetuximab for the treatment of metastatic colorectal cancer.

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Additional therapy for young children with spastic cerebral palsy: a randomised controlled trial.

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Screening for type 2 diabetes: literature review and economic modelling.

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Hormonal therapies for early breast cancer: systematic review and economic evaluation.

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Adalimumab, etanercept and infliximab for the treatment of ankylosing spondylitis: a systematic review and economic evaluation.

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Prenatal screening and treatment strategies to prevent group B streptococcal and other bacterial infections in early infancy: cost-effectiveness and expected value of information analyses.

By Colbourn T, Asseburg C, Bojke L, Philips Z, Claxton K, Ades AE, *et al.*

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Clinical effectiveness and cost-effectiveness of bone morphogenetic proteins in the non-healing of fractures and spinal fusion: a systematic review.

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A randomised controlled trial of postoperative radiotherapy following breast-conserving surgery in a minimum-risk older population. The PRIME trial.

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No. 32

Current practice, accuracy, effectiveness and cost-effectiveness of the school entry hearing screen.

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The clinical effectiveness and cost-effectiveness of inhaled insulin in diabetes mellitus: a systematic review and economic evaluation.

By Black C, Cummins E, Royle P, Philip S, Waugh N.

No. 34

Surveillance of cirrhosis for hepatocellular carcinoma: systematic review and economic analysis.

By Thompson Coon J, Rogers G, Hewson P, Wright D, Anderson R, Cramp M, *et al.*

No. 35

The Birmingham Rehabilitation Uptake Maximisation Study (BRUM). Home-based compared with hospital-based cardiac rehabilitation in a multi-ethnic population: cost-effectiveness and patient adherence.

By Jolly K, Taylor R, Lip GYH, Greenfield S, Raftery J, Mant J, *et al.*



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