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The Birmingham rehabilitation uptake maximisation study (BRUM): a randomised controlled trial comparing home-based with centre-based cardiac rehabilitation

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ABSTRACT

Objective: To compare the outcomes of home-based (using the *Heart Manual*) and centre-based cardiac rehabilitation programmes.

Design: Randomised controlled trial and parallel economic evaluation.

Setting: Predominantly inner-city, multi-ethnic population in the West Midlands, England.

Patients: 525 patients referred to four hospitals for cardiac rehabilitation following myocardial infarction or coronary revascularisation.

Interventions: A home-based cardiac rehabilitation programme compared with centre-based programmes.

Main outcome measures: Smoking cessation, blood pressure (systolic blood pressure (SBP), diastolic blood pressure (DBP)), total cholesterol (TC) and high-density lipoprotein (HDL)-cholesterol, psychological status (HADS anxiety and depression) and exercise capacity (incremental shuttle walking test, ISWT) measured at 12 months. Health service resource use, quality of life utility and costs were quantified.

Results: There were no significant differences in the main outcomes when the home-based was compared with the centre-based programme at 12 months. Adjusted mean difference (95% CI) for SBP was 1.94 mm Hg (-1.1 to 5.0); DBP 0.42 mm Hg (-1.25 to 2.1); TC 0.1 mmol/l (-0.05 to 0.24); HADS anxiety -0.02 (-0.69 to 0.65); HADS depression -0.35 (-0.95 to 0.25); distance on ISWT -21.5 m (-48.3 to 5.2). The relative risk of being a smoker in the home arm was 0.90. The cost per patient to the NHS was significantly higher in the home arm at £198, (95% CI 189 to 208) compared to £157 (95% CI 139 to 175) in the centre-based arm. However when the patients' cost of travel was included, these differences were no longer significant.

Conclusions A home-based cardiac rehabilitation programme does not produce inferior outcomes when compared to traditional centre-based programmes as provided in the United Kingdom.

Exercise-based cardiac rehabilitation has been shown to be an effective intervention to reduce mortality following myocardial infarction and revascularisation.[1] In spite of its potential benefits and recommendation by UK national guidance,[2][3] only a minority of eligible patients complete a programme of cardiac rehabilitation following their myocardial infarction (MI) or revascularisation, with uptake and adherence particularly low in women, older patients and people from ethnic minority groups.[4] Home-based cardiac rehabilitation programmes might

address the problems of poor uptake and adherence by fitting in better with people's lifestyles.

Although there have been a small number of randomised controlled trials comparing home-based with centre-based cardiac rehabilitation these trials have been generally underpowered and heterogeneous in their interventions.[5–12] It is therefore not possible on the basis of this evidence to comment on the relative effectiveness of home-based compared to centre-based cardiac rehabilitation delivery.

We hypothesised that a home-based programme might provide an effective alternative to centre-based programmes and not have inferior outcomes and improve uptake and adherence rates and be comparably cost-effective. We tested these hypotheses in the Birmingham Rehabilitation Uptake Maximisation (BRUM) study, which was a randomised trial that aimed to compare the outcomes of home-based and centre-based cardiac rehabilitation in terms of cardiac risk factors and adherence to rehabilitation 12 months after recruitment post-MI, percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG).

METHODS

The methods of the study have been reported in detail elsewhere.[13] Ethical approval was granted by the local research ethics committees.

Recruitment and randomisation

Individual patient randomisation was undertaken by an independent clinical trials unit using a computerised programme and minimising for age, sex, ethnicity, initial diagnosis and hospital of recruitment. Patients were eligible if they were referred in the two-year period from 1 February 2002 to the cardiac rehabilitation programme in one of four hospitals in the West Midlands health region, following an MI, PTCA or CABG within the previous 12 weeks and were not considered to be high risk for a home-based exercise programme.

Interventions

The rehabilitation programmes included exercise, relaxation, education and lifestyle counselling.

The four centre-based programmes varied in length, including nine sessions at weekly intervals, 12 sessions over 8 weeks and 24 individualised sessions over 12 weeks. Programmes commenced between 4 weeks and 8 weeks following the cardiac event. Patients exercised to 65–75% of their

predicted maximal heart rate and the exercise element of the sessions lasted from 25 minutes to 40 minutes plus warm-up and cool-down elements.

The home-based programme consisted of a manual, three home visits (at 10 days, 6 weeks and 12 weeks) and telephone contact at 3 weeks. Patients who had had an MI were discharged home with the *Heart Manual* (2nd edition)[14] or an adapted version of the *Heart Manual* for revascularisation patients which commenced on their discharge. Additional visits were made as deemed necessary by the rehabilitation nurse. All the nurses who provided the home-based cardiac rehabilitation programme attended a two-day training course run by the originators of the *Heart Manual*. The manual encourages patients to build up their exercise gradually to achieve a minimum of 15 minutes of moderately intense activity daily.

Outcome measures

As cardiac rehabilitation is a broad intervention with a focus on increasing physical exercise, smoking cessation, improvement of diet and a reduction in psychological morbidity, it is not appropriate to give primacy to one outcome measure. Primary outcomes at 12 months were cardiac risk factors: serum cholesterol, blood pressure, distance walked on the incremental shuttle walking test (ISWT),[15] psychological morbidity assessed by the Hospital Anxiety and Depression Scale (HADS)[16] and smoking cessation validated by urinary nicotine metabolites.[17]

Secondary outcomes included (i) self-reported behaviours: diet measured using a food frequency questionnaire, physical activity using the exercise component of the Health Behaviours Profile[18] (a modified Godin questionnaire[19]); (ii) healthcare utilisation; (iii) cardiac symptoms: frequency and severity of angina and shortness of breath; (iv) body mass index (BMI); (v) health-related quality of life (Euroqol EQ5D)[20]; (vi) death and cardiac events; (vii) employment status.

Power calculations

Our initial estimate assumed 30% attrition at one year due to death and loss to follow-up and required a sample size of 650. However, with a high follow-up rate at 6 months we were able to reduce the required sample size to 525 participants and exceeded the 450 evaluable participants at 12-month follow-up as required in the initial power calculation. Details of the power calculation have been published previously.[13]

Data collection

An eligibility form was completed on all patients post-MI/PTCA/CABG. Baseline data were collected before randomisation and included primary and secondary outcomes (with exception of the ISWT, which was omitted because patients were recruited a few days post-MI, which was too early for the ISWT to be undertaken). Baseline clinical indices, including weight, height and blood pressure were measured and the result of the serum cholesterol level from their recent admission was obtained. Severity of condition was assessed using the Killip Score[21] (post-MI) or the number of vessels revascularised (post-PTCA or CABG).

Definition of adherence to cardiac rehabilitation was confined to the physical activity component. We sent questionnaires at 6 weeks, 9 weeks and 12 weeks after recruitment asking about intensity and duration of physical activity undertaken in the previous 7 days. Only one questionnaire was sent, with no reminder, because of the close timing of the three questionnaires.

Data on outcomes were measured by questionnaire and clinical assessment at a hospital site at 6 months and 12 months by a nurse blinded to the treatment allocation of the patient. If a patient was too unwell or was unwilling to attend the hospital assessment a home visit was undertaken and the ISWT omitted.

Statistical analysis

All data were analysed by intention to treat. The primary analysis investigated unadjusted differences at 12-month follow-up in primary and secondary outcomes.

Secondary analyses were conducted for each primary outcome measured on a continuous scale, with differences in means between the two groups investigated using analysis of covariance to take into account the baseline measurements and adjusted for the minimising variables (logistic regression was used to provide adjusted analyses for smoking cessation). Interaction terms between these variables and rehabilitation setting were included to investigate pre-specified possible differences in treatment effect between subgroups of patients. Where hypothesis tests were carried out, these were at the 5% level for primary outcome variables and at the 1% level for interaction terms.

A sensitivity analysis was undertaken in which absent values were assumed to be "missing not at random".[22] Regression based models at 12 months were developed to assess the relation between covariates and outcome measures in completers.[23] Missing cases were substituted with a predicted outcome value.

Economic study methods

Resource usage was defined from both NHS and societal perspectives. Resource use data were collected from the cardiac rehabilitation staff on patients' use of the rehabilitation services and from participants on their use of general practice and hospital services and drug use for secondary prevention and employment status. Travel costs and time were based on distances from patients' addresses to the relevant centre. Hospital records were used to check the number of attendances at the hospital rehabilitation programmes of trial participants and self reported hospital admission data. The nurses who provided the home programme recorded the number of visits and telephone calls made to each patient.

Staff costs were based on the number and grade of staff employed. Staff costs per hour, distinguishing whether patient contact or not, were based on figures by Netten and Curtis, which includes overheads.[24] Travel costs were based on NHS costs for nurses and Automobile Association rates for patients.

The direct cost per patient in the home arm comprised the cost of each home visit and associated telephone calls, the cost of the nurse's travel and travel time, as well as the cost of the *Heart Manual* (including training). The direct cost in the hospital arm within the NHS perspective comprised the cost per rehabilitation session in each hospital multiplied by the number attended (see table 1 on *Heart* website). The estimated cost of patients' travel to the hospital was added to this to obtain a societal perspective. To obtain total NHS costs, three further headings were added: cardiac-related hospital admissions, use of primary care (GP and practice nurse visits) and drugs for secondary prevention. These are all for the 12 months of the study. The unit costs are shown in table 2 on *Heart* website.

Change in EQ5D was based on use of both the 6-month and 12-month values using area under the curve. Data were available

Figure 1 Flow of patients through the Birmingham rehabilitation uptake maximisation (BRUM) study. CABG, coronary artery bypass graft; DNA, did not attend; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty.
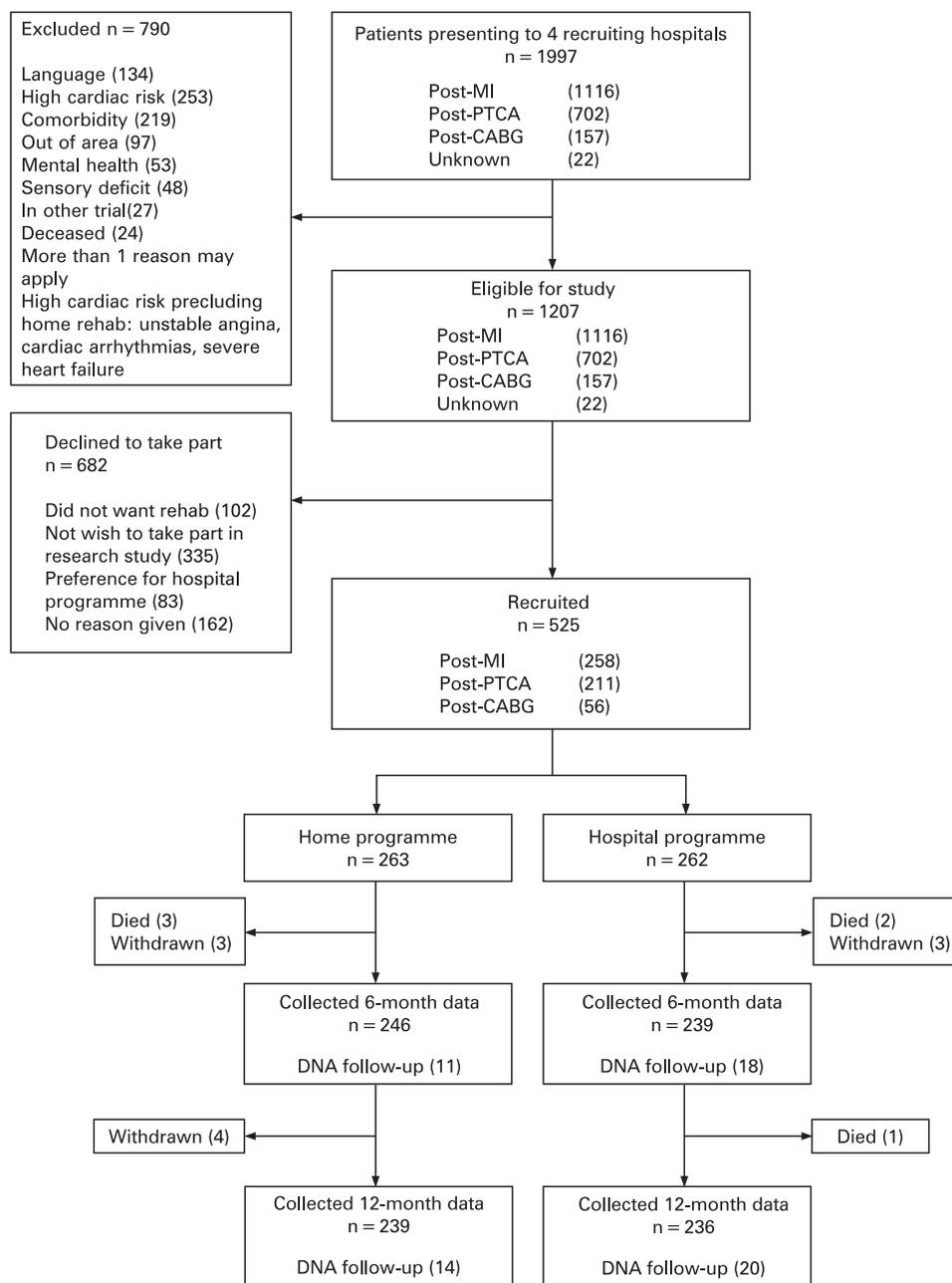
for 492 patients (247 in home and 245 in hospital arms) with 33 patients with less than two EQ5D values excluded. These were split equally between the study arms. For seven patients for whom only baseline and six- month EQ5D data were available, the latter were carried forward to 12 months.

Mean changes in cost and in EQ5D (12 months compared to baseline) in each arm of the trial were bootstrapped and tested for difference using independent two-group T tests.

The ''base-case'' case analysis was the comparison between home and hospital rehabilitation, costed as in the trial, plus other cardiac-related NHS costs and inclusion of patients' travel costs in the hospital, hereafter referred to as the societal perspective. Sensitivity analysis scenarios included a pro-hospital one based only on the direct costs to the NHS of providing rehabilitation services and one pro-home in which the costs of home visits were replaced by hypothetical telephone consultations.

RESULTS

In all, 1997 patients presented post-MI or revascularisation, of whom 1207 (60%) were eligible for home exercise and 525 randomised, of whom 475 (91.5% of live patients) were followed up at 12 months. Figure 1 shows the flow of participants through the trial and table 1 shows the baseline characteristics of cases. There were no significant differences in the characteristics at baseline between patients allocated to the home-based and centre-based arms. During the 12 months of the trial, 11 patients (4%) crossed over from the home to a hospital programme but were analysed on an intention to treat basis. In eight cases patients had developed additional cardiac complications, requiring closer monitoring.

Primary outcome measures

There were no significant differences in the systolic blood pressure (SBP), diastolic blood pressure (DBP) total cholesterol

Table 1 Baseline characteristics by study group

	Home-based (n = 263)	Centre-based (n = 262)
Sex, males n (%)	203 (77.2)	199 (76.0)
Age, mean (SD)	60.3 (10.5)	61.8 (11.0)
Ethnicity, n (%)		
White	211 (80.2)	207 (79.3)
Asian	43 (16.3)	46 (17.6)
Other	9 (3.4)	8 (3.0)
In paid employment, n (%)	109 (41.5)	111 (42.4)
Diagnosis, n (%)		
MI	129 (49.0)	129 (49.2)
PTCA	101 (38.4)	110 (42.0)
CABG	33 (12.5)	23 (8.8)
Medical history, n (%)		
MI	43 (16.5)	54 (20.7)
CABG	16 (6.1)	10 (3.4)
PTCA (angioplasty)	24 (9.2)	24 (9.3)
Diabetes	35 (13.4)	36 (14.1)
Smoking history, n (%)		
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)
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 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 depression score, mean (SD)	4.92 (3.40)	4.76 (3.27)
Clinical indices		
Systolic BP, mean (SD) n	124.00 (17.27)	123.57 (18.32)
Diastolic BP, mean (SD) n	72.45 (11.09)	72.07 (10.55)
Total cholesterol, mean (SD) n	4.75 (1.25)	4.75 (1.35)
HDL cholesterol ,mean (SD) n	1.21 (0.55)	1.26 (0.71)
BMI, mean (SD) n	28.07 (4.94)	27.72 (4.88)
Killip Index (post-MI), mean (SD) n	1.12 (0.37)	1.09 (0.34)
No of vessels treated by PTCA, mean (SD)	1.24 (0.48)	1.18 (0.46)
No of vessels treated by CABG, mean (SD)	2.74 (0.93)	3.05 (1.54)

BMI, body mass index; BP, blood pressure; CABG, coronary artery bypass graft; HADS, Hospital Anxiety and Depression Scale; HDL, high-density lipoprotein; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty.

or high-density lipoprotein (HDL)-cholesterol, HADS scores, distance walked on the ISWT or smoking cessation between the home-based and centre-based groups, either unadjusted or when adjusted for the baseline value, age, sex, diagnosis, ethnicity and centre (table 2).

An interaction test revealed a significant difference ($p<0.01$) in SBP at 12 months between randomisation arm and diagnosis. Participants who were post-MI had a lower mean SBP at 12 months in the home-based than centre-based arm, post-revascularisation patients had a lower SBP in the centre-based arm. No interactions with study group were seen for ethnic group, age group, gender or centre for any of the primary outcomes.

Secondary outcomes
Self-reported diet, self-reported physical activity and shortness of breath did not differ between the groups (details in table 3 on *Heart* website). Participants in the home-based arm reported more chest pain on movement ($p = 0.04$). The number of cardiac events experienced was small, with three deaths in each arm by 12-month follow-up. More patients in the home arm had a revascularisation (n = 36 *v* 26, $p = 0.1$) and more had an MI (n = 9 *v* 4, $p = 0.2$). There were no serious adverse events associated with either arm of the trial.

Changes in risk factor status over time
Participants within the home-based arm of the trial had significant improvements in their mean HADS anxiety score, total cholesterol and HDL-cholesterol and smoking cessation from baseline to 12-month follow-up. Both SBP and DBP increased significantly (table 3). Similar changes were seen in the participants in the centre-based arm.

Adherence to the rehabilitation programmes
In keeping with the earlier start of the home-based programme, significantly more of the participants in the home arm reported undertaking at least three episodes of at least 15-minutes' duration of physical activity in the previous 7 days at 6 weeks (95.2% *v* 85.1%, $p = 0.01$), but the difference was no longer present at 12 weeks (90.1% *v* 93.4%, $p = 0.3$). Participants in the home arm reported a significantly higher exercise score than those in the centre-based arm at 9 weeks median (IQR) 5 (3–7) *v* 3 (3–6) in the centre-based arm ($p = 0.01$).

Participants allocated to be offered the centre-based arm attended 66% of scheduled rehabilitation sessions; 73 (28%) did not attend any of the supervised sessions. In the home-based

Table 2 Primary outcome measures at 12 months

	Home-based CR			Centre-based CR			Mean difference (95% CI of mean difference)	Adjusted mean difference* (95% CI of adjusted mean difference)
	Mean	SD	No	Mean	SD	No		
SBP (mm Hg)	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 (mm Hg)	74.94	9.82	235	74.21	10.66	232	0.73 (−1.13 to 2.59)	0.42 (−1.25 to 2.09)
Total cholesterol 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	406.8	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 0.9† (0.5 to 1.85)

*Adjusted for baseline score, age, sex, diagnosis, ethnicity and centre, except for the ISWT which had no baseline score.
†RR of being a smoker in home arm v centre-based.
CI, confidence interval; CR, cardiac rehabilitation; DBP, diastolic blood pressure; HADS, Hospital Anxiety and Depression Scale; ISWT, incremental shuttle walking test; RR, relative risk; SBP, systolic blood pressure; SD, standard deviation.

Clinical trials

Table 3 Within-group differences in primary outcomes at 12 months

	No	Baseline Mean (SD)	12 Months Mean (SD)	Difference* (95% CI)	p Value
Home programme					
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	212	7.91 (4.5)	6.35 (4.5)	−1.56 (−2.07 to −1.05)	<0.001
HADS depression	222	4.85 (3.3)	4.61 (4.0)	0.24 (−0.23 to 0.71)	0.3
Total cholesterol	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, n (%)	263	94 (35.7%)	49 (21.5%)	−14.2% (−22.4 to −6.0)	<0.001
Centre-based programme					
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	223	7.12 (4.14)	5.91 (4.4)	−1.22 (−1.75 to −0.68)	<0.001
HADS depression	224	4.53 (3.13)	4.73 (3.6)	0.21 (−0.23 to 0.64)	0.4
Total cholesterol	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, n (%)	262	85 (32.4%)	45 (19.5%)	12.9% (−20.8 to −5.0)	<0.001

*Positive result indicates an increase in the mean value from baseline to follow-up.
CI, confidence interval; DBP, diastolic blood pressure; HADS, Hospital Anxiety and Depression Scale; HDL, high-density lipoprotein; SBP, systolic blood pressure; SD, standard deviation.

arm participants received an average of 4.8 (SD 1.5) home contacts. While 241 (96.1%) of the home-participants received five contacts (by visit or telephone) with a cardiac rehabilitation nurse, only 147 (56.1%) of the centre-based participants attended this number of classes (p<0.001). At 6 months 15.2% of patients allocated to the home programme were attending some form of group-based exercise (either a phase IV cardiac rehabilitation programme or classes at a leisure centre) compared to 32.5% of patients allocated to the centre-based programme.

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, total cholesterol and HADS anxiety and depression scores (proportion missing ranging from 10% to 15%). Re-analysis with the imputed values did not alter the interpretation of the results. Sensitivity analysis of costs is reported below.

Health service resource use
There were no significant differences in the health service resource use between the two groups in terms of hospital admissions, primary care visits and use of secondary preventive medication. Time off work did not differ between the groups (table 4 on *Heart* website).

Costs and cost-effectiveness
The change in EQ5D from baseline to 12 months was slightly higher in the centre-based arm but was not statistically significant, consistent with the clinical outcome results reported above. Restricting the costs to those of the NHS providing rehabilitation services led to a lower mean cost per patient in the hospital arm at £157 (95% CI 139 to 175) compared to £198 (95% CI 189 to 208) in the home arm (p<0.05). However when all costs including those to patients of travel to the centres was included (societal cost per patient), the hospital arm cost £896 (95% CI 745 to 1047) per patient compared to £807 (95% CI 684 to 930) in the home arm, making the hospital arm more costly, but with overlapping confidence intervals.

The mean cost per patient in each model was sensitive to how the service was organised. If telephone consultations were assumed to replace all the nurse visits in the home arm, the cost per patient would have fallen below that for the centre-based arm and vice versa if hospital staff required extra time to prepare for rehabilitation sessions. In practice, the mean cost per patient will depend largely on how the service is organised.

DISCUSSION
In this study, of low to moderate risk post-MI and revascularisation patients, we found no statistically significant or clinically meaningful differences in cardiac risk factors, adherence to physical activity, self-reported health behaviours and in cardiac events in patients invited to undertake a home-based programme of cardiac rehabilitation compared to those invited to a centre-based (predominantly hospital) programme. Similarly, neither quality-adjusted life-years (QALYs) nor societal cost per patient differed significantly between arms. Given the low uptake and adherence to hospital-based cardiac rehabilitation, increased availability of home-based cardiac rehabilitation might help to improve uptake and adherence. An audit in a rural part of the United Kingdom found that 57% of patients offered and accepting cardiac rehabilitation chose the home programme[25] and we found a very high acceptance rate of home contacts by the patients randomised to the home programme.

The confidence intervals (CI) around the BP and ISWT mean that we cannot fully exclude a possible clinically significant difference.[26] We also identified more cardiac events in the home-based arm, but the numbers of events were small, and although not statistically significantly different we were not powered to detect a difference in events. Only one previous trial of home versus hospital cardiac rehabilitation reported deaths[6] and this found no difference in mortality between the study groups.

Our results are consistent with those of other trials comparing home-based with centre-based cardiac rehabilitation for MI. In particular, the two trials using the Edinburgh *Heart Manual* in post-MI patients, only in more rural and affluent settings than ours, found broadly similar results.[6 27] Bell[6] reported similar improvements in functional capacity in the

patients randomised to the home and hospital arms, with no statistical difference between these groups.[6] Dalal and Evans[25] reported a significantly greater improvement in exercise capacity in patients in the home rehabilitation arm from 3 months to 9 months of follow-up compared to the hospital group and similar and significant improvements in the HADS depression score, quality of life after myocardial infarction score and total cholesterol in both groups.[25] Ours is the first trial to report the comparative effectiveness of centre-based and home-based rehabilitation using the *Heart Manual* for post-revascularisation patients. Other comparisons of home-based and centre-based cardiac rehabilitation have included programmes of greater intensity than are commonly provided in the United Kingdom,[5 8–12] but have also failed to find significant differences in exercise capacity between patients attending the home-based and centre-based programmes.

As a control group (no rehabilitation) would not have been ethical given the strength of evidence of exercise-based and comprehensive cardiac rehabilitation in reducing mortality post-MI,[1] we cannot completely exclude the possibility that the changes in cardiac risk factors from baseline to follow-up might have occurred as part of the normal recovery process. However, this is unlikely given the strong evidence for the benefits of centre-based cardiac rehabilitation.[1] A previous trial of the *Heart Manual* reported a significantly greater improvement in functional capacity in patients randomised to receive the *Heart Manual* compared to a control group.[6] 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 randomised controlled trials of hospital cardiac rehabilitation compared with usual care and similar to the changes in the intervention arms.[6 28–31] While our study did not have a baseline value for exercise capacity we did find a significant (p<0.01) improvement in self-reported exercise in both the home-based and centre-based arms from baseline to one-year follow-up.

No statistically significant differences were found between the two arms in terms of costs from a societal perspective. Mean total cost per patient was higher in the hospital-based service, although the mean direct cost of rehabilitation services provided was slightly lower.

Limitations of the economic analysis have to do with heterogeneity of services and costs within the hospital arm and with travel costs that were estimated rather than reported. Patient travel costs were important in the hospital arm, but were estimated on the basis of distance from hospital and based on private car cost per kilometre. Although patients were asked in a questionnaire about costs incurred as a result of their rehabilitation programme, relatively few completed this question with only 88 (34%) of the centre-based participants citing travel costs. The addition of data on patient preferences, which may have influenced decisions to participate in the study, would have been interesting, but has been explored in another study.[32]

The costs of the home programme were very similar to those reported in another UK study using the *Heart Manual* (CHARMS); however the centre-based costs in our study were lower (£157 versus £200).[32] Both BRUM and CHARMS adopted a bottom-up costing approach and reported lower rehabilitation costs than those calculated from a 2002 national audit of cardiac rehabilitation programmes.[33] Using a top-down costing method this report estimated total costs (2001/2 prices) of £186 per patient referred to the most common type of rehabilitation programme, and thus included all the cardiac rehabilitation elements, whereas BRUM only costed the phase III rehabilitation classes of the centre-based programme. Sensitivity analysis

showed that the mean cost per patient depends on the detail of how services are organised locally.

The study was not powered to look at subgroups and we found an unexpected interaction between the rehabilitation group and the index condition (MI/revascularisation) for blood pressure. We have undertaken an analysis of potential contributing causes, particularly the utilisation of medications with an anti-hypertensive effect and the distribution of diabetic patients between the trial groups, but have been unable to explain the interaction. Given the number of end-points it could have occurred by chance, but it may deserve investigation in the future.

The proportion of patients taking secondary preventive medications (antiplatelet agents, cholesterol lowering agents, β-blockers and angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor antagonists) was higher in the BRUM study than reported by recent primary care-based studies and did not differ between the study arms.[34–36]

Traditionally, hospital-based programmes measure adherence by the number of sessions attended. However, using contact with rehabilitation professionals to define adherence is likely to over-estimate the adherence to exercise in the home arm. While the home-based group reported more physical activity (weighted for intensity) in the earlier rehabilitation period, this did not translate into better exercise capacity at follow-up. As there was no difference between groups in self-reported physical activity at follow-up it is probable that the behaviour change was not sustained. Another study using the *Heart Manual* in the United Kingdom reported a greater adherence to the home programme than the hospital programme, with 87% of those who chose the home programme completing it (as measured by self-completion of the logs within the manual).[25] Also the greater attendance at phase IV cardiac rehabilitation by the centre-based patients did not lead to better outcomes for this group at the 12-month follow-up.

A strength of this study was its pragmatic nature and its randomised design to an invitation to a rehabilitation setting. We acknowledge that the centre-based programmes were of a lower intensity and frequency than those used in the trials on which the evidence base for cardiac rehabilitation was based and in three of the hospitals are lower than the 16 sessions recommended by the SIGN guidelines. However, the two types of rehabilitation we have compared are similar in intensity, duration and content to the actual provision of rehabilitation programmes in the United Kingdom, which makes our results broadly generalisable to the United Kingdom.[4 37] In addition, the interactions analysis we undertook did not find any significant differences between the centres for any of the primary outcome measures, despite differences in the number of centre-based sessions offered. The low level of provision of cardiac rehabilitation in the United Kingdom has been highlighted in a recent audit[4] together with data that current cardiac rehabilitation programmes are unable to provide adequate provision for even the minority of patients who do attend.[37] In addition, while only 56.1% of the patients randomised to be offered the centre-based programme attended five classes or more, this compares well to the 41.3% attending this number in a previous large trial in the United Kingdom.[4] The setting in a multicultural inner city location, with 20% of the sample from an ethnic minority group, also increases the study's generalisability, given the high rate of heart disease in the South Asian population.[38 39] We have also achieved a relatively high follow-up rate and find that the results do not change with the sensitivity analysis using a method to substitute missing values by imputation.

Clinical trials

CONCLUSIONS

Given the lack of differences in outcomes between the different rehabilitation settings, neither model can be concluded to be better. Although this study was not designed to show equivalence, the provision of a home-based service alongside the hospital services would provide choice for patients and might improve uptake and adherence in patients who are not willing or able to attend a hospital.

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