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DOI:
10.1186/1471-2261-3-10

BMC Cardiovascular Disorders

Study protocol

Open Access

Home-based versus hospital-based cardiac rehabilitation after myocardial infarction or revascularisation: design and rationale of the Birmingham Rehabilitation Uptake Maximisation Study (BRUM): a randomised controlled trial [ISRCTN72884263]

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Published: 10 September 2003

BMC Cardiovascular Disorders 2003, **3**:10

Received: 30 June 2003
Accepted: 10 September 2003

This article is available from: http://www.biomedcentral.com/1471-2261/3/10

Abstract

Background: Cardiac rehabilitation following myocardial infarction reduces subsequent mortality, but uptake and adherence to rehabilitation programmes remains poor, particularly among women, the elderly and ethnic minority groups. Evidence of the effectiveness of home-based cardiac rehabilitation remains limited. This trial evaluates the effectiveness and cost-effectiveness of home-based compared to hospital-based cardiac rehabilitation.

Methods/design: A pragmatic randomised controlled trial of home-based compared with hospital-based cardiac rehabilitation in four hospitals serving a multi-ethnic inner city population in the United Kingdom was designed. The home programme is nurse-facilitated, manual-based using the Heart Manual. The hospital programmes offer comprehensive cardiac rehabilitation in an out-patient setting.

Patients: We will randomise 650 adult, English or Punjabi-speaking patients of low-medium risk following myocardial infarction, coronary angioplasty or coronary artery bypass graft who have been referred for cardiac rehabilitation.

Main outcome measures: Serum cholesterol, smoking cessation, blood pressure, Hospital Anxiety and Depression Score, distance walked on Shuttle walk-test measured at 6, 12 and 24 months. Adherence to the programmes will be estimated using patient self-reports of activity.

In-depth interviews with non-attendees and non-adherers will ascertain patient views and the acceptability of the programmes and provide insights about non-attendance and aims to generate a theory of attendance at cardiac rehabilitation. The economic analysis will measure National Health Service costs using resource inputs. Patient costs will be established from the qualitative research, in particular how they affect adherence.

Discussion: More data are needed on the role of home-based versus hospital-based cardiac rehabilitation for patients following myocardial infarction and revascularisation, which would be provided by the Birmingham Rehabilitation Uptake Maximisation Study (BRUM) study and has implications for the clinical management of these patients. A novel feature of this study is the inclusion of non-English Punjabi speakers.

Background

Cardiac rehabilitation services aim to facilitate physical, psychological and emotional recovery and to enable patients to achieve and maintain better health[1]. This is achieved through exercise, patient education and advice, relaxation, drug therapy, and specific help for patients with psychological sequelae. [2–4]

The majority of cardiac rehabilitation programmes in the UK are hospital-based combined programmes including exercise, psychological and educational interventions [2–4]. Meta-analyses of the effectiveness of combined programmes suggest that they can achieve a reduction in cardiac mortality of 20–26% over a 1–3 year time frame [5–7]. Psychological and educational interventions, including patient education, counselling and behavioural interventions have been addressed in two meta-analyses [8–10] and systematic reviews [11,12]. These have shown that cardiac rehabilitation can improve blood pressure and serum cholesterol levels [8–10] psychological well-being [9,11] and patient knowledge[12] and estimated a relative reduction in recurrent non-fatal cardiac events of 46% [9], in cardiac mortality by 34% [10] and mortality of 19% [8].

Relatively few studies have evaluated the effectiveness of cardiac rehabilitation following revascularisation and there is still insufficient evidence about the effects of cardiac rehabilitation on survival. Cardiac rehabilitation rehabilitation programmes have reported some benefits in aerobic capacity [13] a reduction of smoking and lower blood pressure [14,15], lower anxiety scores[16] and improvement in lipoprotein patterns [17].

Home-based cardiac rehabilitation

Trials comparing home-based cardiac rehabilitation programmes to usual care (controls) have reported significantly greater improvements in exercise capacity[18,19], systolic blood pressure [20] and lower anxiety [21] in the patients participating in home rehabilitation compared to the controls at follow-up. Six randomised controlled trials comparing home-based to supervised centre-based cardiac rehabilitation programmes have been published[18,19,22–25]. These studies report similar improvements in exercise capacity, systolic blood pressure or serum cholesterol at follow-up between the home and centre-based groups. A home-based programme using the Heart Manual (West Lothian Health Care Trust, Scotland) reported significantly reduced hospital admissions in the home-based group during the first 6-months of follow-up compared to patients receiving usual care [18] and in a cardiac rehabilitation programme following CABG the patients in the home-based arm reported a significantly improved quality of life compared to patients attending a hospital programme [25].

The trials suffer from being an exercise-only rather than comprehensive intervention [23,26,27], have small numbers [21,28], and a high proportion of patients were excluded on health grounds [23,26], sex and age [23,26] Lewin's Heart Manual, which was developed for use at home, has been evaluated against control groups [23,26], and hospital-based rehabilitation in an unpublished study (Jennifer Bell, personal communication). The latter study reports no difference in the primary outcome measure of symptom limited exercise time between hospital and home groups during 1 year follow-up. This trial excluded patients aged 65 years or greater and took place in the south of England. Contrary to some concerns, home-based exercise programmes have not reported an increased risk of sudden death, but the trials have not been large, and there is insufficient evidence in this area [23,24]

Uptake and adherence to cardiac rehabilitation

It is clear that many people who would benefit from cardiac rehabilitation are not receiving it. This is due to both service and patient factors. Uptake rates for cardiac rehabilitation have been reported to range from 15–59% [29,30] Many services concentrate on relatively low risk, white middle aged patients, whilst women and the elderly are less likely to be invited [29,31]

There is a distinct lack of information in the published literature about uptake in people from ethnic minority groups in the UK, although anecdotal data from those programmes serving large ethnic minority populations in Birmingham suggest that they are under-represented, particularly the women. A study in the USA reported a higher drop-out rate of black women from a cardiac rehabilitation programme compared to white women, despite a greater prevalence of risk factors in the black women [32].

Poor uptake is also related to service factors, such as the availability and accessibility of a programme [33], the strength of a physician's recommendation to attend [31,34] and treatment by a general physician, rather than a cardiologist [29]. Patient factors include the reported feeling amongst the elderly and women that they will be out of place [35] and beliefs about whether their illness was amenable to cure or control [36]. Socio-demographic factors such as deprivation [29], level of education [37] and spouse involvement [38] are significant predictors of uptake.

Of those patients who do attend hospital cardiac rehabilitation the drop-out rates from exercise programmes range from 20% in the first three months to 50% at 6 months to a year[39]. Dropout rates have been reported to be higher in high intensity exercise programmes and poorly organised programmes. Smokers, patients who have had more that one MI [39–41], and women are more likely to drop out [42]. Qualitative insights are limited [43–45], but suggest that patients' behaviour results from confusion about the aims, content and structure of rehabilitation programmes, their own beliefs or the information given by health professional as to the 'seriousness' of their cardiac event. Reasons for non-adherence to cardiac rehabilitation given by Asian patients include not having been formally invited to rejoin a programme if they missed a session and difficulties in contacting telephone helplines[46].

There is little research looking at ways of increasing uptake and adherence to cardiac rehabilitation programmes. Physical difficulties, such as difficulty parking and lack of spouse support have been cited as reasons for dropping out of an exercise programme [33]. Qualitative interviews were carried out with survivors of myocardial infarction in Scotland and identified 38% who did not want to attend a group for rehabilitation [35]. Thus, there is clearly a need to evaluate programmes that might be more inclusive, achieve higher uptake rates in certain groups, and minimise subsequent dropouts amongst those who have started a rehabilitation programme. It is possible that home programmes might be more effective as a result of greater participation or 'uptake'.

Cost and cost-effectiveness of cardiac rehabilitation

Insufficient evidence relevant to the UK exists as to the cost-effectiveness of cardiac rehabilitation. A survey of program costs in the UK has been reported [47]. A cost-effectiveness and cost-utility analysis in America [48] was based on one meta-analysis [6], and the costs have been recalculated to reflect UK costs[49]. The UK results suggest a cost per life year gained at three years of €15,700 and a cost per QALY of €6,900. A randomised controlled trial based in Italy reported lower direct costs in the home programme, as a result of lower programme costs and reduced health care utilisation [19].

What is known about current provision?

A number of recent surveys of cardiac rehabilitation programmes in the UK have highlighted deficiencies [2,3,50]. Practice in Scotland was found to fall short of that advocated in guidelines and was usually more limited in its provision than had shown benefits in randomised controlled trials [3]. Practice was generally found not to be individually tailored to patients and many patients were excluded due to age or illness [2,50] The UK National Service Framework for Coronary Heart Disease sets the goal for all patients discharged from hospital with a primary diagnosis of acute myocardial infarction or revascularisation to be offered appropriate cardiac rehabilitation and sets targets for behavioural change at one year in these patients.

Methods/Design

BRUM is a randomised controlled trial (RCT) of home-based versus hospital-based cardiac rehabilitation in a multi-ethnic population, funded by the NHS Research and Development Programme. The primary research question seeks the relative effectiveness and cost-effectiveness, of home-based compared with hospital-based cardiac rehabilitation, and the reasons for non-participation.

To answer these questions BRUM will determine whether there are differences at 6 months, 1 and 2 years following hospital- and home-based cardiac rehabilitation in objective cardiac risk factors; patient reported uptake and adherence. It will also explore whether these differ between patient groups (the elderly, women and patients from ethnic minority groups). Secondly, the relative costs of hospital- and home-based cardiac rehabilitation from both the patients' and NHS perspectives will be determined, as well as qualitative insights into the reasons for non-participation in the cardiac rehabilitation programmes. Lastly, BRUM will ascertain whether there are differences in cardiac clinical events (MI/death from cardiac cause) at 2 years following hospital- and home-based cardiac rehabilitation.

Table 1: Inclusion and exclusion criteria for BRUM study

Inclusion criteria	**Exclusion criteria** (applied by a cardiologist)
Diagnosis within previous 3 months of a first or subsequent myocardial infarction (MI)	Case-note reported dementia
Diagnosis within previous 3 months of a first or subsequent percutaneous transluminal coronary angioplasty (PTCA)	Unstable angina
Diagnosis within previous 3 months of a first or subsequent coronary artery bypass graft (CABG)	Cardiac arrhythmias
English or Punjabi speakers	Severe heart failure
	Sight defects of sufficient severity to prevent the reading of the Heart Manual
	Severe hearing impairment

Study Design

Inclusion and exclusion criteria are described in table 1.

The four hospitals from which patients are recruited are in the West-Midlands in the U.K. Three serve deprived mixed race inner city populations, up to 25% from minority ethnic groups, mainly South Asians and Afro-Caribbeans. Given the high incidence of coronary heart disease in people of South Asian origin, and the low uptake of cardiac rehabilitation in people living in deprived circumstances [29], this makes it an ideal population in which to study uptake of cardiac rehabilitation. In addition, work done locally has identified that South Asians are less likely to take exercise, and have a lower awareness of what constitutes a healthy diet than the white population [51,52].

The study has three parts. Firstly, a pragmatic randomised controlled trial comparing the clinical effectiveness of home- and hospital-based strategies. Secondly, the results of this will be used to inform an economic model, which will explore the generalisability of the results and to compare these with other coronary heart disease interventions. Thirdly, a qualitative study running alongside the trial, to gain insights into reasons for poor uptake and lack of adherence.

Randomised controlled trial design

The trial is a pragmatic, two arm randomised controlled trial of patients following MI or revascularisation, using individual patient randomisation. Patients are identified by the rehabilitation nurses following hospital admission for MI or PTCA. Patients following CABG are normally followed-up and referred for rehabilitation at their hospital of origin. All eligible patients will be informed about the study prior to hospital discharge and asked if they would consent to randomisation. For patients who do not speak English, tape recordings of the patient information leaflet are available, and Punjabi speaking nurses are available to answer questions. Patients are not excluded from the study on the grounds of age.

Baseline data are collected prior to randomisation. These include demographic details, disease history and baseline measures of the outcome data. Data for Killip Class and Peel Index Scores[53,54]. (measures of severity of infarction), or numbers of vessels stented or bypassed are collected to check comparability in risk between the groups at baseline.

Patients who consent to randomisation are randomised centrally by computer on an individual basis with stratification by (i) original diagnosis (MI/revascularisation) (ii) age/sex, (iii) ethnicity (Caucasian/Asian/Other) and (iv) hospital of recruitment, using the method of minimisation.

• In one arm patients are invited to the hospital's usual cardiac rehabilitation programme;

• In the second arm patients are invited to undertake a home-based cardiac rehabilitation programme.

The trial design is summarised in Figure 1. Patients who refuse randomisation are offered their respective hospital's usual rehabilitation package.

What are the planned trial interventions?

Both rehabilitation programmes include exercise, relaxation, education and life-style counselling, with referral for psychological treatments as indicated. All patients are seen prior to hospital discharge and provided with information about their condition and counselling about risk factor modification.

• Hospital-based cardiac rehabilitation

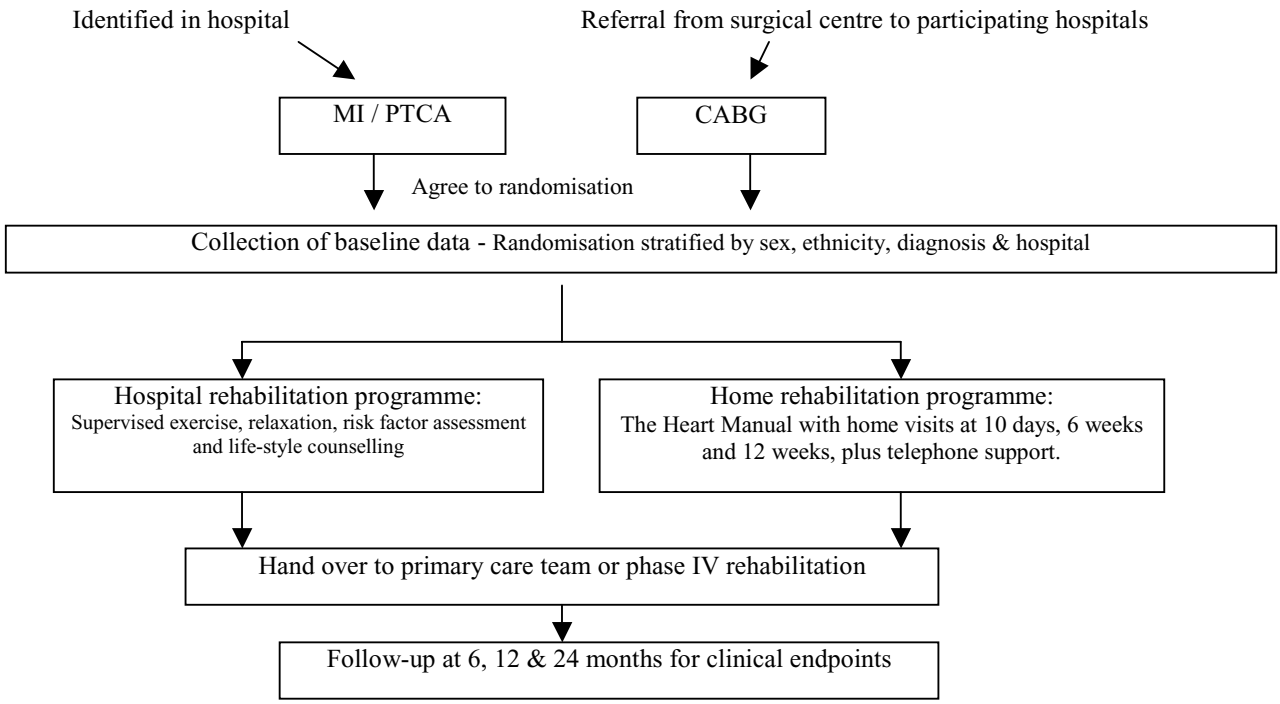

Figure 1
Study outline. CCU: coronary care unit; MI: myocardial infarction; PTCA: percutaneous transluminal coronary angioplasty; CABG: coronary artery bypass graft.

All hospital programmes are working towards complying with the guidance in the National Service Framework (NSF) for coronary heart disease[55]. All hospitals have a protocol for cardiac rehabilitation, but as there are stylistic differences in patient management all analyses will be stratified by hospital.

The four hospitals provide comprehensive cardiac rehabilitation programmes consisting of risk factor counselling, relaxation, and supervised exercise sessions for 6–12 weeks once to twice weekly.

• Home-based cardiac rehabilitation

This consists of a manual, home visits and telephone contact. Patients who have had an MI are discharged home with 'The Heart Manual' (West Lothian Health Care Trust). Those who have had a revascularisation have a similar Heart Manual designed for this patient group. The Heart Manual is a facilitated home-based programme for the first 6 weeks following MI or revascularisation and 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.

Information about how to contact their rehabilitation nurse will be provided. Home visits take place at 1–2 weeks and 6 and 12 weeks, and telephone contact at 3 weeks during which the rehabilitation nurse discusses the contents of the manual with the patient and partner or other relative, and sets individual objectives with the patient with respect to smoking cessation, diet and exercise. Patients with no telephone have home visits instead of telephone contacts. Patients who speak Punjabi and have an insufficient command of English have contact with a rehabilitation nurse who speaks Punjabi. An audiotape in Punjabi accompanies the manual in patients with a limited command of English (as many non-English speakers of this age-group are also illiterate). Patients in

Table 2: Outcome measures of BRUM study

Primary outcome measures	Secondary outcome measures
Serum cholesterol	BMI (Body Mass Index)
Blood pressure (assessed according to British Hypertension Society Guidelines)	Self-reported diet
Exercise capacity as assessed by the shuttle-walk test (the association with VO2 max has been validated in patients with heart failure and following CABG [76])	Self-reported exercise (Godin[77])
Psychological morbidity: Hospital Anxiety and Depression Scale[78] (Asian patients will complete a translated version)	Health care utilisation (primary and secondary care and phase IV rehabilitation)
Cotinine validated smoking cessation	Cardiac symptoms (angina and shortness of breath)
	Use of secondary preventive medication
Adherence	Quality of life (Euroqol EQ5D)
Self-reported physical activity at 6, 9 and 12 weeks	Death and cardiac events
	The Global Mood Scale to English speaking patients (at 6 months only)
	Quality of life (Short Form-12) (at 6 months only)
	Patient satisfaction with the programmes (at 6 months only)

home and hospital-based groups are asked to complete the modified Godin questionnaire at 6, 9 and 12 weeks to record activity undertaken in the previous week. Hospital-based rehabilitation runs for 9–12 weeks. The Heart Manual covers the first 6 weeks post-event, but we have extended contact with patients in the home programme until 3–4 months to coincide with the end of the hospital programme.

Recruitment will take place over 18 months. Follow-up will take place by postal questionnaire and clinical assessment at 6 months, 1 year and 2 years. Patient records will be flagged by the ONS to identify deaths from cardiac causes.

Outcome measures

The primary outcome measures include: (i) cardiac risk factors; (ii) adherence measures. Secondary outcome measures are for (iii) self-reported behaviour, symptoms and secondary preventive medication; (iv) quality of life; (v) death and other cardiac events. Because of comparability differences and the rarity of death and infarction, cardiac risk factors are given primacy (Details are given in table 2).

If a cardiac rehabilitation 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[40,56–65]. At 1 year mortality rates are low (6% in Jolly 1999 [66]) and it is unlikely that we would see a reduction in cardiac events. It is also possible that revascularisation rates could be associated with participation in a particular rehabilitation programme. Since the interventions are multi-factorial and aims are broad, the use of a number of cardiac risk factors as primary outcome measures at 6 months and 1 and 2 years follow-up are justified.

Patient uptake and adherence to the programmes are of primary interest. However, there will be difficulties in obtaining unbiased measures of these, as attendance at a hospital programme cannot be equivalently compared to acceptance of a home visit. Patient completed activity questionnaires (modified Godin at 6, 9 and 12 weeks) are used for both groups to provide a comparison of activity and thus of adherence to the programmes.

To reduce the potential for bias in measuring outcomes clinical follow-up will be undertaken by an individual who has not provided the rehabilitation support.

Sample size

Assuming a conservative estimate of 30% attrition at 1 year (a lower attrition would increase the power of the study) due to death and loss to follow-up (15% in Jolly 1999 [66]), a sample size of 650 patients (450 evaluable at 1 year) would have 90% power, at the 5% significance level, to detect the differences tabulated (table 3) (population standard deviations estimated from Jolly 1999 [66]).

Statistical analysis

All data will be analysed by intention to treat. All analyses will be stratified by centre. Comparisons between the primary outcome measures of cardiac risk factors will be made at three separate time points, 6 months, one year and two years, to assess both short and longer-term effects of the two rehabilitation strategies.

Table 3: Size of differences detected by sample size

Endpoint	Difference	Assumptions	Precision of estimate	
			95%	99%
Mean serum cholesterol/ mMol/L	0.4	Sd[a] = 1.3	± 0.24	± 0.32
Systolic blood pressure/ mmHg	6	sd = 21	± 3.9	± 5.1
Shuttle-walk test/10 metre shuttles	6	sd=[b]20 or sd = * 40	± 3.7 ± 7.4	± 4.9 ± 9.7
HADS[c] anxiety	1.5	sd = 4.5	± 0.83	± 1.1
HADS[c] depression	1.5	sd = 4.0	± 0.74	± 0.97
Smoking cessation	20% (Jolly [66])	45% smokers at baseline (effective sample size approx 200) 50% give up in hospital-based group	9%, 33%	5%, 37%

[a] Standard deviation [b] SD 19 reported in Keell *et al* [76], 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 (apart from sex) and thus likely to be a substantial underestimate of the standard deviation for our population. Further estimates are given assuming a standard deviation for our population of 40. The true value is likely to lie somewhere between these extremes [c] Hospital Anxiety and Depression scale

For cardiac risk factors measured on a continuous scale (serum cholesterol, systolic blood pressure, exercise capacity, HADS anxiety and depression), differences in means between the two groups will be investigated. Baseline measurements for exercise capacity will not be available as patients are randomised approximately 4 days post-MI and the day after PTCA which is too early to undertake an exercise test. As the sample is large and randomised we would not expect baseline differences between the groups. For the other measures, analysis of covariance will be 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[67]. Differences in smoking cessation will be assessed amongst those who were smokers at baseline using the Cochran-Mantel-Haenszel^2 test for a difference in proportions; confidence intervals will be calculated using the formula due to Cochran.

Secondary analyses will be conducted for each primary outcome measure adjusting for diagnosis (MI/revascularisation), age, sex and ethnicity, as well as centre (logistic regression will be used to provide adjusted analyses for smoking cessation). Interaction terms between these factors and rehabilitation setting will be included to investigate possible differences in treatment effect between subgroups of patients. Although the power to detect modest interactions will be low, we are 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.

Throughout the analysis emphasis will be placed on estimation rather than hypothesis testing. Where hypothesis tests are carried out, these will be 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 use of somewhat more conservative significance levels (1% for primary outcomes), this adjustment is too conservative when outcomes are positively correlated, as they will be in this trial. Although alternative methods of adjustment are available, the performance of these methods depends heavily on the underlying data structure[68]. 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 are investigating what has been termed 'multiple univariate hypotheses' rather than a true (single) multivariate hypothesis; the univariate methods outlined above are thus more appropriate[69].

Economic Evaluation

Costs will be assessed from two perspectives: that of the NHS and societally. NHS costs will be based on resource inputs costed up to include labour and overhead costs. Societal costs will be ascertained qualitatively, with the particular emphasis of describing whether the costs to an individual of participating in a cardiac rehabilitation programme is a factor affecting the uptake of and adherence to that programme. If outcomes differ between the models, a cost effectiveness evaluation will explore incremental cost effectiveness using the primary measures noted above, clinical risk factors and uptake. If clinical outcomes do not differ a cost minimisation analysis is appropriate for cost per patient. The incremental effects and costs of any increased take-up in one arm will be analysed.

Comparing the costs of the existing hospital services with the home based service requires the use of identical meth-

ods for costing and exploration of how trial based cost estimates might apply in practice. Bottom-up costing will be employed, based on detailed data collection of resources used, mainly staff inputs by duration and type. Any knock-on effects on use of other services would be identified and costed. The estimation of non-staff costs in each programme (overheads, administration, accommodation and travel) will also be based on observed resource use but also explored in a costing model. The model will enable the cost impact of changes in levels of service and in location to be quantified. The generalisability of the results will be explored by locating the costs in a national context by a national survey of costs of all English cardiac rehabilitation programmes.

Qualitative Study

The qualitative part of the study seeks insights into the reasons for non-participation or non-adherence by patients in the cardiac rehabilitation research programmes with the objective of generating a theory of adherence to cardiac rehabilitation. Qualitative methodologies offer the most appropriate way to elicit their reasons for non-participation as they enable people's beliefs, knowledge and the meanings they ascribe to their health experiences and behaviours to be explored and understood[70]. The methods of grounded theory will be used[71,72] to guide sampling, data collection and data analysis. The qualitative interviewing technique of semi-structured interview[73] will be used, which is firmly established in the social sciences and increasingly valued in health and medical research.

Participants and sampling

From the initial sample of all study participants details will be kept of those (i) who decline to commence a rehabilitation programme and (ii) those who commence but do not adhere. Patients in the home-based arm will be defined as declining the programme if they do not accept any home visits. They will be defined as non-adhering if, in the opinion of the cardiac rehabilitation nurse, they do not read the Heart Manual or use the tapes or attempt the exercise programme or cease participation during the 12 week programme. Patients in the hospital arm will be defined as non-adhering if they do not complete the rehabilitation programme for reasons other than ill-health. Within each of these two categories (declining and non-adhering patients) we will seek a purposive sample of 10 patients from each of four groups (women, the elderly, minority ethnic group patients, younger white men) for initial sampling (40 patients in total). Patients will be randomly selected from the lists and contacted for interview until ten have been interviewed. This will be followed by seeking a further theoretical sample[72] within each group with selection of patients guided by emerging data analysis in order to extend and challenge earlier data and interpretation, and test the integrity and credibility of the developing analysis. This theoretical sample may include patients with particular experiences that it becomes important to seek as the analysis develops. It is anticipated that up to 10 further respondents in each of the four groups may be sought in this way (maximum 80 participants), before interviewing is no longer generating new concepts and is discontinued i.e. theoretical saturation[71].

Methods and analysis

Data from patients will be collected by confidential, face-to-face interview[73] in patients' own homes, using an interview topic prompt. The interview topic prompt will be developed using existing knowledge from the literature to derive initial topic areas, and then modified and refined by interviewing in a pilot phase of the study a sample of patients who had not commenced or adhered to a previous cardiac rehabilitation programme at one of the study hospitals. The interviews will follow broad topic areas based upon the study objectives, but encourage respondents to discuss their perceptions and experiences freely. Their recent cardiac event and arrangements for rehabilitation will be specifically focussed on and explored in depth. The acceptability of rehabilitation programmes and perceptions of these and any preference they initially had for the hospital or home programme will be explored. Interviews with patients who wish to be interviewed in their own language will be carried out either by a bilingual researcher or a researcher assisted by bilingual interpreters with appropriate language skills following processes for good practice[72]

All interviews will be audio taped and transcribed into English, using commercial transcribing services where appropriate. Transcriptions will be read and checked for accuracy by the research fellow and the text then entered into a computerised database using the Atlas ti software package for qualitative data analysis.

Data analysis will acknowledge the impact of the use of interpreters where appropriate[74]. Constant comparative analysis will be used to interpret the data[75]. To maximise theoretical sensitivity[72], researchers from different disciplinary and professional backgrounds will contribute to the development of the analysis and conceptual framework. Coding processes[72] will be aided by application of the Atlas ti software in identifying emerging key categories and concepts from the data. These will be compared across the different interview data sources and established concepts in the literature. Data collection and analysis will be iterative, occurring as data collection in the interviews proceeds with new data being used to challenge, assess or confirm the emerging analysis. Concepts identified will be

integrated into themes providing a structure for presentation of findings.

Discussion

The BRUM trial seeks to recruit patients from an inner city multi-cultural population and to include patients who are unable to speak or read English well, but do speak Punjabi (the most frequently spoken minority language locally). Since literacy rates are low in the non-English speaking population this has required a taped version of the Heart Manual in Punjabi and the need for the primary outcome measurement tools to be available in Punjabi. As a result, a translation and validation study of a Punjabi version of the Hospital Anxiety and Depression Scales (HADS) had to be undertaken prior to the start of the study. The final results of the study will not be available before 2006.

Competing interests

None declared.

Authors' contributions

The BRUM Steering Committee consists of: S. Greenfield, K. Jolly (Principal Investigator), D. Lane, K.W. Lee, G.Y.H. Lip, J. Mant, J.P. Raftery, J. Sandercock, A.J. Stevens (Chair of Steering Committee), R.S. Taylor. KJ wrote the initial protocol, designed the study and drafted this paper, GL participated in the design of the study, the writing of the initial protocol and drafted this paper, JS wrote the statistical elements of the initial protocol and designed the study, AS assisted in the design of the study and the writing of the initial protocol, SG designed and wrote the qualitative element of the initial protocol and assisted with the design of the study, JR designed and wrote the economic element of the initial protocol and assisted with the design of the study, JM assisted in the design of the study and the writing of the initial protocol, RT advised on the outcome measures used, DL assisted in the design of the study and the writing of the initial protocol, KL supervises the recruitment of patients into the trial. All authors read and approved the final manuscript.

Acknowledgements

The BRUM study is funded by the NHS HTA Programme. The views and opinions expressed in this paper do not necessarily reflect those of the Department of Health. National Heart Research has funded the production of the Heart Manual for patients who have had a revascularisation procedure.

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Pre-publication history

The pre-publication history for this paper can be accessed here:

http://www.biomedcentral.com/1471-2261/3/10/prepub