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

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
26/08/2009

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 99/32/09

Study information

Scientific Title

Acronym
BRUM

Study objectives
Aim:
What is the relative effectiveness and cost-effectiveness, taking uptake into account, of home-based versus hospital-based cardiac rehabilitation? What are reasons for non-participation?

To answer these questions we will determine:
1. Whether there are differences at six months and one year following hospital- and home-based rehabilitation in:
1.1. Objective cardiac risk factors
1.2. Patient reported uptake and adherence
1.3. And whether these differ between patient groups (the elderly, women and patients from ethnic minority groups)
2. The relative costs of hospital- and home-based cardiac rehabilitation from both the patients' and NHS perspectives
3. Qualitative insights into the reasons for non-participation in the cardiac rehabilitation programmes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular diseases: Heart disease

Interventions
Hospital-based versus home-based cardiac rehabilitation programmes provided by specialist cardiac rehabilitation nurses. Both programmes will include exercise, relaxation, education and life-style counselling, with referral for psychological treatments as indicated. The home programme will be based around a patient-held manual (The Heart Manual for MI patients) with home visits and telephone support from the cardiac rehabilitation staff. A manual will be developed for revascularisation patients.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary outcomes at six months and one year:
1. Cardiac risk factors (serum cholesterol, blood pressure, exercise capacity measured by the shuttle test, psychological status-HADS, smoking cessation)
2. Uptake and patient reported adherence to each programme
3. Patient satisfaction and perceptions of the programmes
4. Quality of life
5. Use of secondary preventive medication
6. Health care utilisation and cardiac events

Costs would be assessed from two perspectives: that of the NHS and socially. NHS costs will be based on resource inputs (time with cardiac nurses, other NHS personnel, travel time, drugs, use of other NHS services) costed up to include labour and overhead costs. Societal costs will extend NHS costs to include costs to patients and to any other relevant agencies (to be decided via patient interviews and costed as for the NHS). If the outcomes differ between the models, a cost-effectiveness evaluation will explore incremental cost-effectiveness using the outcome measures noted above. Otherwise a cost-minimisation analysis is appropriate. In either case, modelling will explore the generalisability of the results by locating the costs in a national context by collecting data from other English rehabilitation programmes by means of a survey. The results will be compared with the range of other CHD interventions, linked to work already in progress (JR's involvement in a national cost effectiveness model funded by DoH).

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/10/2001

Completion date

28/02/2006

Eligibility

Key inclusion criteria
Consecutive patients admitted to two acute hospitals in the West-Midlands, serving a multi-ethnic patient catchment, following myocardial infarction (MI) or revascularisation (percutaneous transluminal coronary angioplasty [PTCA]/coronary artery bypass graft [CABG]).

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
650

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/10/2001

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Public Health & Epidemiology
Birmingham
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Sponsor information

Organisation
Department of Health (UK)

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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	design and rationale at	10/09/2003		Yes	No

Other publications	recruitment analysis at	17/05/2005	Yes	No
Results article	results	01/01/2009	Yes	No