## **Rural and Remote Health**

The International Electronic Journal of Rural and Remote Health Research, Education, Practice and Policy

MEDLINE listed

FRAME

#### **REVIEW ARTICLE**

# Home versus hospital-based cardiac rehabilitation: a systematic review

J Blair<sup>1</sup>, H Corrigall<sup>2</sup>, NJ Angus<sup>3</sup>, DR Thompson<sup>4</sup>, S Leslie<sup>2</sup>

<sup>1</sup>Centre for Health Science, University of Stirling, Highland Campus, Inverness, Scotland <sup>2</sup>NHS Highland, Raigmore Hospital, Inverness, Scotland <sup>3</sup>Centre for Health Science, University of Stirling, Highland Campus, Inverness, Scotland <sup>4</sup>Department of Health Sciences and Department of Cardiovascular Sciences, University of Leicester, Leicester, UK

Submitted: 26 May 2010; Revised: 17 December 2010; Published: 6 April 2011

Blair J, Corrigall H, Angus NJ, Thompson DR, Leslie S

Home versus hospital-based cardiac rehabilitation: a systematic review *Rural and Remote Health* 11: 1532. (Online), 2011

Available from: http://www.rrh.org.au

#### ABSTRACT

Comprehensive cardiac rehabilitation has positive effects on many cardiac risk factors (physical activity, smoking status, cholesterol, anxiety and depression) and can lead to improvements in mortality, morbidity and quality of life. Most formal cardiac rehabilitation in the UK is offered within a hospital or centre setting, although this may not always be convenient or accessible for many cardiac patients, especially those in remote areas. The proportion of eligible patients who successfully complete a cardiac rehabilitation program remains low. There are many reasons for this but geographical isolation and transport issues are important. This systematic review examines the current evidence for home- versus hospital-based cardiac rehabilitation. Home-based cardiac rehabilitation offers greater accessibility to cardiac rehabilitation and has the potential to increase uptake. While there have been fewer studies of home-based cardiac rehabilitation, the available data suggest that it has comparable results to hospital-based programs. Many of these studies are small and heterogeneous in terms of interventions but home-based cardiac rehabilitation appears both safe and effective. Available evidence suggests that it results in longer lasting maintenance of physical activity levels compared with hospital-based rehabilitation and is equally effective in improving cardiac risk factors. Furthermore, it has the potential to be a more cost-effective intervention for patients who cannot easily access their local centre or hospital. Currently



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

home-based cardiac rehabilitation is not offered routinely to all patients but it appears to have the potential to increase uptake in patients who are unable, or less likely, to attend more traditional hospital-based cardiac rehabilitation programs.

Key words: community, home, home-based cardiac rehabilitation, United Kingdom.

## Introduction

The benefits of cardiac rehabilitation (CR) in the treatment and prevention of cardiac disease are well established. Recent systematic reviews and meta-analyses<sup>1-3</sup> show that patients who participate in cardiac rehabilitation have significant reductions in mortality and morbidity including improvements in exercise tolerance, symptoms, blood lipid profiles, blood pressure and psychosocial wellbeing. However, despite the evidence and inclusion of cardiac rehabilitation in national rehabilitation guidelines<sup>4-7</sup>, there is a lack of standardisation with respect to what a cardiac rehabilitation program should include, and participation of eligible patients in cardiac rehabilitation remains poor<sup>8</sup>.

In the UK, the issue of rural health has taken a back seat to ever-increasing centralist policies<sup>9</sup>. Therefore, there is a need to examine modes of service provision within the more remote communities. The delivery of specialist care is particularly challenging, given that many practitioners in rural areas are generalists. Rural populations may themselves introduce barriers to the uptake of specialist care. Reluctance to use services, combined with the importance of maintaining independence, a decline in community spirit and the fear of being a burden, all raise potential barriers to the delivery of high quality specialist care<sup>10</sup>. Conversely, evidence also suggests that rural populations tend to be accepting of the fact that living in rural areas necessitates an 'element of personal responsibility in accessing services'<sup>11</sup>, and that new technology is generally welcomed to improve and provide health care as close as possible to home<sup>11</sup>.

Cardiac rehabilitation has traditionally been viewed as a hospital-based intervention. However, if rehabilitation is to be truly patient-focused, then there is a strong case for increased home-based provision, particularly for rural populations. There are several barriers to the uptake of hospital-based cardiac rehabilitation<sup>12,13</sup>, including distance and ease of access<sup>14,15</sup>, and while these are issues for those in urban environments (eg poor public transport, difficulty parking) those barriers may represent an even greater challenge for those living in remote and rural locations<sup>16,17</sup>.

Home-based programs, for example the Heart Manual<sup>18</sup> and the Angina Plan<sup>19</sup>, have been developed to provide a nurseled, community-based, self-help program for patients who may not be able to repeatedly attend a hospital-based program. Both the Heart Manual and Angina Plan have been shown to provide effective strategies for a self-help program for patients unable to attend a hospital-based rehabilitation program<sup>18-20</sup>. However, few data are available to assess the efficacy of such interventions in rural patients<sup>16</sup>. With the increasing financial burden of coronary heart disease worldwide, the development of an affordable, acceptable and method of community-based cardiac appropriate rehabilitation is of significant importance.

This article systematically reviews the current evidence pertaining to community- and home-based cardiac rehabilitation and focuses particularly on issues for remote and rural populations.

## Methods

#### Search strategy

An electronic search was performed of PubMed, EMBASE, CINAHL and the Cochrane Controlled Trials Register (CCTR) for articles between the dates of January 1970 to March 2010. The following search limits were introduced for



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

the electronic search: involved human subjects, article published in English, involved adult subjects (>19 years). The following MeSH terms were used: myocardial infarction/ischaemia, angioplasty, coronary artery bypass graft, heart failure, cardiac rehabilitation, exercise rehabilitation, exercise therapy, psychotherapy, community rehabilitation. Once a full list of articles was obtained, these were checked for duplication and for the inclusion and exclusion criteria (below). Initially article abstracts were reviewed to obtain relevant research articles which involved home-based rehabilitation and the outcome measures required (below). In total, 35 full-text articles were retrieved and reviewed for suitability for this review. Reference lists of appropriate studies were also hand-searched to identify further research studies for potential inclusion. This method identified 5 relevant articles which were included in the review process (Fig1).

#### Inclusion criteria

The inclusion criteria for the present review were as follows:

- Human subjects
- Adults (>19 years old)
- English language text
- Cardiac rehabilitation study in a home or community setting
- Patient had been discharged from hospital and article focused on post-discharge care
- Patients following acute myocardial infarction (MI), percutaneous transluminal coronary angioplasty, coronary artery bypass graft (CABG), coronary heart disease (CHD), or congestive heart failure (CHF)
- At least one of the following outcome measures had to be included:
  - o Physical activity levels
  - Psychological status (anxiety, depression, quality of life, distress)
  - Clinical outcomes including (but not exclusively) cholesterol levels, blood

pressure, oxygen consumption (VO<sub>2</sub>), hospital re-admissions, smoking status.

#### Definition of home-based cardiac rehabilitation

In many studies the definition of 'home', 'community' and 'hospital' CR was not clear. For the purposes of this review a pragmatic approach was taken; 'home based' was defined as CR which was delivered either in the patients' home or in a local, non-hospital location while 'hospital based' was defined as CR delivered in a hospital or medical centre setting.

#### Results

In total, 131 articles were identified by electronic search and 17 of these met the inclusion criteria and were deemed suitable for review, with a further 5 articles sourced from a manual search of reference lists (Fig1). There were 8 studies that directly compared home-based with hospital-based cardiac rehabilitation participants, and the remaining studies compared home rehabilitation with a control group (which varied from hospital-based cardiac rehabilitation to 'usual' or 'standard' care), although this was often poorly defined (Table 1).

#### Mortality

In general, participation in CR is associated with a relative reduction in mortality of approximately 25%. In terms of absolute risk reduction there is great heterogeneity between studies due to different study populations with mortality rates varying from 3.8% in the Ontario Exercise Heart Study<sup>21</sup>, to 26.4% in a Helsinki-based study<sup>22</sup>. Nevertheless, there appears to be little difference between hospital and home-based cardiac rehabilitation in terms of reduced mortality or cardiovascular event rates<sup>23,24</sup>.

The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

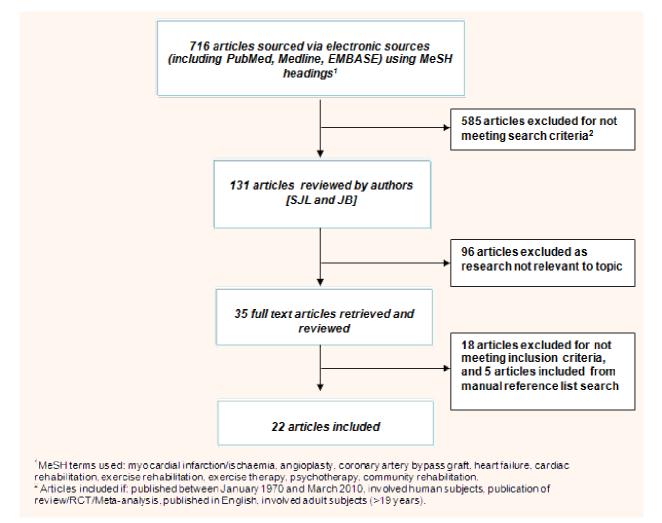


Figure 1: Literature review search strategy flowchart.

# Cardiovascular risk factors (cholesterol, high blood pressure, smoking)

Telephone follow up and home-based cardiac rehabilitation can produce a greater reduction in serum cholesterol when compared with usual care<sup>25,26</sup>. Similar reductions in cholesterol levels are also observed following hospital-based rehabilitation<sup>23,27</sup>. A key study by Jolly et al<sup>23</sup> directly compared home- with hospital-based programs. The results showed a reduction in blood pressure following both forms of intervention, with no difference in blood pressure reduction at 6 months, suggesting home rehabilitation is as effective at reducing blood pressure as a hospital-based intervention. A reduction in smoking habit can be seen in both home- and hospital-based groups with a similar improvement in both groups when compared with baseline levels. However, there was no improvement observed in patients who received a GP-based form of rehabilitation, suggesting a more focused or intense approach is required<sup>28</sup>.

#### Prevalence of angina

A significant reduction in frequency of angina was reported by an early community-based study<sup>29</sup>. A more recent study

The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

by Jolly et al<sup>23</sup> also reported an improvement in the frequency of angina, along with self reported chest pain on movement and shortness of breath. Improvements in all these factors help to improve quality of life of the cardiac patient. There were no clinically significant differences when comparing patients who completed their rehabilitation at home with those who did so in hospital.

#### Hospital re-admissions

Hospital re-admissions are often measured as a primary outcome<sup>24,30-32</sup>. During the initial 6 week period of a homebased study, 5% (n=3) from the intervention group had planned re-admissions<sup>32</sup>, compared with 14% (n=11) from the control group. At 6 months follow up, the intervention group still had fewer in-patient admissions and significantly fewer emergency admissions. A similar intervention study by Sinclair et al<sup>24</sup> examined patient use of hospital services (Table 1). There were 25% (n=35) re-admitted in the treatment group compared with 41% (n=51) from the usual care group within the first 100 days following discharge, suggesting that home visits reduce subsequent admission to hospital<sup>24</sup>. One Australian community-based study found that patients who attended a rehabilitation program were admitted less frequently and spent less time in hospital than those receiving usual care<sup>30</sup>. Over a 12 month period, less than 1% of patients from the intervention group and 4% from the control group were re-admitted. This impressive reduction in hospital re-admissions was important when assessing the efficacy and cost-effectiveness of home- or community-based rehabilitation. However, it should be noted that, of the 954 patients registered in the program, 621 attended fewer than four sessions so were excluded from the final study analysis.

#### Anxiety, depression and quality of life

Both home and hospital cardiac rehabilitation reduce anxiety and depression<sup>23,27</sup> with no difference in effect between modalities. However, there also appears to be a natural temporal improvement in anxiety and depression in cardiac patients following an event<sup>33</sup>. Similar improvements in quality of life are observed when comparing home- with hospital-based rehabilitation<sup>23,27,34,35</sup> Marchionni et al<sup>35</sup> also found improvements in both home and hospital groups' quality of life, and noted an improvement in younger patients who had received no formal rehabilitation. This reinforces similar findings in post-CABG patients working with the Heart Manual<sup>36</sup>. A significant improvement in quality of life can be seen with heart failure patients receiving home-based physical activity intervention when compared with an education-only group<sup>37</sup>. These data would appear to support the inclusion of exercise in home rehabilitation programs.

#### Physical activity

When comparing home rehabilitation with comprehensive hospital-based care there appears to be little or no difference in physical activity outcomes between the two<sup>23,34-36,38,39</sup> suggesting that there is no difference between these two approaches to cardiac rehabilitation and that both are effective. Home cardiac rehabilitation interventions are certainly associated with improvements in physical activity levels, from an improved 6 min walk test28, increase in estimated VO<sub>2</sub><sup>25,36</sup> increased daily physical activity index<sup>40</sup>, and improved functional capacity in heart failure patients<sup>37</sup> after completing a rehabilitation program. Patients involved in a focus group after completing the 12 week Heart Manual program found the exercises to be well planned but were worried about exercising on their own, especially in the early days<sup>41</sup>. However, home-based exercise may have longer lasting effects. While Marchionni et al<sup>35</sup> observed an improved total work capacity in both hospital and homebased groups, at 12 months post-discharge, total work capacity had reverted to baseline levels in the hospital group, but not in the home-based patients. These data suggest that home-based rehabilitation exercise may have longer lasting effects than hospital-based rehabilitation in terms of activity levels. It has been suggested by patients that home rehabilitation is seen as 'more of a lifestyle change...rather than treatment<sup>41</sup>. Patients feel the onus of control themselves during home rehabilitation; whereas, in hospital others are 'in control<sup>41</sup>.



Author/s (year) [ref no.]	Study design	Sample size	Characteristics	Control group	Intervention group	Outcome
Arthur et al. (2002) [36]	RCT	242	Patients 35- 49 days post- CABG and who passed cycle based exercise test.	Hospital group were expected to attend classes 3 times per week for 6 months of an hour per session.	Patients assigned to the home group attended individual 1 hour exercise consultation with an exercise specialist. Patients kept an exercise log and were telephoned every 2 weeks by the exercise specialist to monitor progress.	Peak VO <sub>2</sub> improved significantly in both groups after 6 months of training. The home group reported receiving greater total social support than the hospital group at 3 and 6 months. The home group also reported a greater improvement in HRQoL by 6 months compared with hospital patients.
Bethell & Mullee (1990) [29]	RCT	200	Acute MI males ≤65 years.	Short talk on suitable unsupervised exercise.	3 month course of 3 times per week circuit training which commenced at 5-7 weeks post-MI.	At 3 month follow up, intervention patients experienced 10% drop in angina prevalence, a rise in perceived energy levels and an increase in predicted $VO_2$ max.
Bethell et al (1999) [17]	RCT	200	Acute MI males ≤65 years.	Short talk on suitable unsupervised exercise.	3 month course of 3 times per week circuit training which commenced at 5-7 weeks post-MI.	Observed over 11 years via questionnaire, no significant difference for non-fatal re-infarction nor for long-term mortality between control and intervention patients.
Canyon & Meshgin (2008) [30]	Observational Study	954	Diagnosis of angina, IHD, MI, AF, cardiac arrest, PCI, valve replacement, two IHD risk factors.	Attended no formal rehabilitation sessions.	1 session per week for 7 weeks. Including 1 hour exercise and 1 hour education per session. Commenced 3-6 weeks after registration to program.	19% of control group re-admitted, 6% of intervention group re-admitted (within 2-14 months after initial registration).
Carlson et al (2000) [39]	Randomised trial	80	Post - cardiovascular surgery or event. Male and female 35-75 years referred to outpatient CR, low -moderate risk.	Commenced 5 weeks post event/surgery. Underwent traditional protocol involving 3 ECG monitored exercise sessions per week for 6 months.	Commenced 5 weeks post event/surgery. Underwent modified protocol, involving 3 ECG monitored sessions a week for 1 month, then weaned onto an off-site exercise regime with educational support and phone calls.	Modified protocol patients had higher rates of off-site exercise over 6 months and total exercise in first 3 months. Modified protocol patients less likely to drop out.
Dalal et al (2007) [27]	Comprehensive cohort study	230	All patients admitted with uncomplicated MI.	Hospital based, commenced 4-6 weeks post-discharge. Attended classes once a week for 8-10 weeks. Each class lasted 2 hours.	Home based – patient seen during hospital stay by CR nurse and introduced to Heart Manual to use over 6 weeks. Involved structured exercise, stress management and education. Phone calls at weeks 2, 3, 4 and 6 by nurse.	Outcome measures taken at 9 months include HAD, QoL and serum total cholesterol. No significant difference in any outcome between home and hospital based patients. Also, no significant difference in outcomes between those patients who were randomised and those who chose their own mode of CR.

## Table 1: Summary of studies from systematic review $(n=22)^{17,23-43}$



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

Author/s (year) [ref no.]	Study design	Sample size	Characteristics	Control group	Intervention group	Outcome
Frasure- Smith et al (1997) [43]	RCT	1376	Acute MI not related to a coronary procedure.	Control group received usual care, which did not include telephone monitoring or home visits.	Patients contacted 1 week post discharge, then every month for 1 year. Patients identified as being at risk of psychological distress following completion of general health questionnaire were visited and followed up by nurse as required.	No overall survival impact. Higher cardiac and all cause mortality among women in the intervention group. No evidence of benefit or harm to male participants. The program's impact on anxiety and depression was small
Gary et al (2004) [37]	RCT	32	Women >50 years with class II or III heart failure.	Received 12 weekly home visits to administer education program and to perform vital heart and lung assessments.	Home based low to moderate intensity exercise (40% intensity, 3 days per week for 12 weeks) and education program (consisting of HF disease management and women's health issues).	Intervention group improved distances in the 6 min walk test (840ft up to1043ft intervention group; 824ft down to 732ft in control group) at completion of 12 week program. Improved QoL in intervention group using the Living with Heart Failure and Geriatric Depression Scale (at completion of 12 week program and at 3 month follow up).
Higgins et al (2001) [25]	RCT	99	Routinely scheduled PCI patients.	In hospital patients received one to one (x 2) education sessions (45 min pre-PCI, 60 min post-PCI). Patients also received 3 month post- discharge follow-up phone call.	Same education sessions as control group plus individualised comprehensive CR. Included moderate intensity exercise with graded increases over time and vocational counselling and 3 home visits by a clinician in first 2 months post PCI.	Intervention group – improved serum cholesterol at early follow up (8-26 weeks) and late follow up (36-56 weeks) but not significantly different from the improvement also noted in control group. Improved exercise participation from 35-88%, compared with 53- 59% in control group as being active. Both control and intervention group saw an improvement in functional capacity, as measured by CCS.
Jolly et al (1999) [28]	RCT	597	Post MI patients and recent onset (within 3 months) angina.	No further information on the treatment received by those allocated to control group.	Program to coordinate preventative care led by specialist liaison nurses to improve communication between hospital and general practice, and to help provide structured follow up for patients.	No significant difference between intervention and control groups in smoking, lipid concentrations, BP or fitness levels.
Jolly et al (2007) [23]	Individually randomised trial	525	Post-MI or revascularisation recruited from 4 hospitals over 2 years.	Centre-based comprehensive CR at 4 different locations, ranging from 6 to 12 week programs. Full details given for each program.	Home based via the Heart Manual plus home visits and telephone contact. Commenced on hospital discharge. Heart Manual provides a self help program for 6 weeks post-MI, including education material, home-based exercise program and stress and relaxation management, including a relaxation tape.	No statistically significant difference in any outcome measures between home and centre (taken at 6,12 and 24 months post CR). Primary outcome measures were serum cholesterol, blood pressure, exercise capacity via shuttle walk test, psychological morbidity cotinine- validated smoking cessation.



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

Author/s (year) [ref no.]	Study design	Sample size	Characteristics	Control group	Intervention group	Outcome
Jones et al (2009) [41]	Focus group study	26	16 Hospital program and 10 home program patients (post-MI or revascularisation)	Centre based comprehensive CR at 4 different locations ranging from 6-12 week programs.	Home based via the Heart Manual plus home visits and telephone contact. Commenced on hospital discharge. Heart Manual provides a self help program for 6 weeks post MI, including education material, home-based exercise program and stress and relaxation management, including a relaxation tape.	Common themes between modes of CR included loss of confidence, realising importance of exercise and awareness of the benefits of CR. Themes exclusive to hospital CR included ease of access, enjoyment from group sessions, motivation to attend regular sessions and reluctance to exercise outside hospital environment. Home program patients experiences included unanimous praise for the Heart Manual, helpfulness of relaxation tapes, positive views on nurses support provided and thought the exercises well planned but expressed anxiety when beginning to exercise alone.
Kodis et al (2001) [38]	Retrospective database review	1042	Patients who took part in exercise rehabilitation following CABG.	713 patients took part in clinic-based supervised exercise sessions twice weekly. Patients assessed 6- 8 weeks post CABG and 6 months post-CABG.	Patients (n=329) given a personalised exercise program following assessment by an exercise specialist. Patients were encouraged to exercise 3-5 times per week. The exercise specialist provided follow up phone calls to monitor progress, on average, 2-3 times in the 6 month period.	Following 6 months of exercise rehabilitation, there were substantial improvements in peak VO <sub>2</sub> , peak workload and peak METs in both the home and clinic groups. The supervised groups showed significant improvements in HDL and LDL cholesterol, but the home based patients showed improved HDL only.
Lacey et al (2004) [42]	Controlled observational study comparing two cohorts	152	AMI patients discharged from hospital.	Received standard care as practised at the time for cardiac rehabilitation – no further details given.	Received home-based self care package in the form of the Heart Manual alongside standard cardiac rehabilitation provision.	Following the 3 month intervention patients receiving the Heart Manual, in addition to the standard care, showed a significant improvement in anxiety and depression scores and a small improvement in general health status.
Lear et al (2003) [26]	RCT	302	Male and female patients with IHD.	Usual care group returned to care of family physician.	Extensive Lifestyle Management Intervention (exercise, phone follow ups, lifestyle counselling) versus usual care.	No significant difference in any outcome between control group and intervention.
Marchionni et al (2003) [35]	RCT	270	3 age groups: - middle-aged (45-65) - old (66-75) - very old (>75).	Control group attended a single session on cardiovascular risk factor management with no exercise prescription and returned to the care of their family physician.	<i>Hospital</i> program consisted of 24 endurance style exercise sessions (3 times/ week) and 16 sessions of stretching and flexibility. They also received counselling twice per week. <i>Home</i> program as above for 4-8 sessions. Then patients received an exercise program, a pulse monitor, a cycle ergometer (for 2 months) and a log book to record their HR. Patients were visited by a physical therapist every fortnight.	Outcome measures were taken at the end of the 2 month program, at 6 and 12 months later. Within each age group TWC improved with home and hospital CR and was unchanged in the control group. The improvement was similar in middle- aged and old patients, but was smaller in very old patients. TWC reverted back to baseline by 12 months with hospital CR but not with home CR. HRQoL improved in middle aged and old patients in all 3 groups, but only improved in very old patients who received CR. Costs were lower for home CR.



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

Author/s (year) [ref no.]	Study design	Sample size	Characteristics	Control group	Intervention group	Outcome
Oliveira et al (2008) [40]	Controlled trial	30	Sedentary males from a small rural hospital with recent first MI.	Composed of those declined entry from intervention due to economic, geographical, or other reasons. They received usual care as no elements of standard CR were offered by hospital (69.8 $\pm$ 6.1 years)	12 week program containing education, counselling and a range of education on physical activity. Consisted of group sessions, telephone contacts and home visits. (67.2 years ± 5.4).	PA measured using accelerometer in weeks 1, 6 and 12. Using METs to establish if activity was light or moderate. Intervention group significantly improved PA index (278.2 to 525.5 counts/min/day) and the time spent in moderate intensity PA (from 16.8 to 63.7 min/day). No changes were observed in the control group.
Robertson et al (2003) [32]	RCT	80	Admitted with first MI.	Control group followed the CR program already in place at the local hospital. Patients must wait 6 weeks before participation.	Weekly home visit for 4 weeks post- discharge by nurse to provide a supportive education program. Commenced immediately post-discharge.	Data collected at 6 weeks and 6 months post discharge. Patients who received immediate home based care demonstrated significantly fewer hospital re-admissions to emergency dept at 6 weeks and to inpatient dept at 6 weeks and 6 months post-discharge. There was a complete absence of admissions in the intervention group during the course of the 4 week trial.
Sinclair et al (2005) [24]	Single blind RCT	324	Over 65 years discharged home after suspected MI.	Control group received usual care comprising of general advice, outpatient clinics and access to the local cardiac rehabilitation program offered as per usual practice	Home based nurse-led intervention consisted of everything offered to control group plus at least two home visits after discharge at 1-2 weeks and 6-8 weeks. Extra visits/phone calls were used if the nurse felt a need. Home visits encouraged compliance with treatment, information and education on risk factors and advised on exercise and resumption of ADLs.	At 100 day follow up, no difference in deaths, ADL's or QoL between intervention and control groups. Intervention group had fewer hospital readmissions and fewer days of hospitalisation after initial discharge. Intervention group also had higher rates of return to driving (42/43 compared with 32/43 in control group).



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

Author/s (year) [ref no.]	Study design	Sample size	Characteristics	Control group	Intervention group	Outcome
Smith K et al (2004) [34]	RCT	222	Patients between 35 and 49 days post CABG.	Patients expected to attend supervised exercise classes 3 times per week for 6 months and keep an exercise log book.	Patients in the home based group attended individual 1 hour exercise consultations at baseline and 3 months and were asked to keep a log book of duration, intensity and HR. Patient telephoned every fortnight to monitor progress.	At 12 months follow up (12 months post completion of program, 18 months after baseline measurements), peak VO <sub>2</sub> sustained in home group but declined in hospital CR patients. Physical HRQoL higher in home group at follow up, with mental HRQoL showing minor deterioration over time in both groups. Home patients had higher habitual PA levels than hospital at 12 months.
Taylor et al (1997) [33]	RCT	585	Hospitalised for Acute MI.	Received usual care – no further details specified in study.	Nurse managed, home based multifactorial risk factor reduction program.	Significant reduction in psychological distress variables for all patient groups. Treatment and control groups showed equal levels of improvement.
Young et al (2003) [31]	RCT	146	Confirmed diagnosis of MI, residing in catchment area, eligible for home visits.	Usual care patients were referred to non-invasive cardiac lab, cardiologist follow up and given information on local rehabilitation centre.	Usual care plus 6 home visits by cardiac nurse, communication with the family and education. Referred to as Disease Management Program.	Follow-up period ceased in July 2001. Intervention patients had fewer readmissions (40 vs 80 for control) and fewer readmission days. During first 25 days post-discharge, intervention patients had significantly fewer provincial claims for services (emergency department, diagnostic services or laboratory services). During the follow-up period, there were 147 emergency department encounters for usual care patients, 64 for intervention group.

ADLs, Activities of daily living; AF, atrial fibrillation; BP, blood pressure; CABG, coronary artery bypass graft; CCS, Canadian Cardiovascular Society scale; CR, cardiac rehabilitation; ECG, electrocardiograph; HAD, hospital anxiety and depression; HDL, high density lipoprotein; HR, heart rate; HRQoL, health-related quality of life; IHD, ischaemic heart disease; LDL, low density lipoprotein; METs, metabolic equivalent of task; MI, myocardial infarction; NYHA, New York Heart Association; PA, physical activity; PCI, percutaneous coronary intervention; QoL, quality of life; TWC, total work capacity, VO<sub>2</sub>, oxygen consumption.

#### Cost of rehabilitation

Research comparing home with hospital rehabilitation<sup>23</sup> has determined the average cost per patient to be £198 and £157, respectively. When costs for patient travel and time were included, the cost for hospital rehabilitation rose close to that of the home program (£157-£181). When comparing 6 weeks' provision of the Heart Manual with 8-10 weeks of comprehensive hospital cardiac rehabilitation, Taylor<sup>44</sup> found the home-based approach to be, on average, £30 cheaper per patient. The reasons for this were attributed largely to the reduction in personnel costs for this particular program. Over a 9 month period, there was no significant difference in healthcare costs between the two patient groups.

#### Participation and concordance

Less than 50% of eligible cardiovascular patients benefit from cardiac rehabilitation in most European countries<sup>45</sup> and participation rates remain low in those who are referred. Reasons for non-attendance vary from patients being 'not interested', illness, need to work, re-admission to hospital and transport issues<sup>23,46</sup>. When comparing adherence rates between home and hospital-based interventions, the Birmingham Rehabilitation Uptake Maximisation (BRUM) study found that 96.1% of home participants received 5 contacts with a rehabilitation nurse, whereas only 56.1% of centre-based participants attended this number of classes<sup>23</sup>. For patients living in remote and rural areas, the most prominent barriers are accessibility and distance<sup>15</sup>.

#### Discussion

There are limited data regarding 'home versus hospital' cardiac rehabilitation but both appear to be effective at improving clinical parameters and fitness. Home rehabilitation may prove more successful in maintenance of physical fitness in cardiac patients<sup>35</sup>. The variation in mortality between studies is likely to reflect the lack of standardisation of entry criteria to cardiac rehabilitation programs even within clinical trials. The risk of further cardiac events and death are clearly related to patient

characteristics but also temporal distance from the index event; thus, if there is a delay in recruitment of patients into cardiac rehabilitation, death rates within the program will tend to be lower because a proportion of higher risk patients may have died before commencing cardiac rehabilitation.

Similarly, measurements of the prevalence of angina should be interpreted with caution. While frequency of angina in cardiac patients may be a major factor in their quality of life, angina may increase following successful cardiac rehabilitation because patients are exercising more, or being more socially active. This is particularly true in patients with chronic stable angina, because an increase in the frequency of angina may not actually result in a reduction in quality of life. Frequency of angina should be examined in the context of activity and other quality of life measures. Hospital readmission is an important outcome in terms of costeffectiveness and has arguably greater implications for those living in remote and rural areas. Re-hospitalisation rates following initial recovery from MI range from 5-41%<sup>24,32</sup>. While it is impossible to prevent all hospital readmissions through the use of cardiac rehabilitation programs, the current evidence suggests that communitybased programs, in a variety of forms, are effective in reducing re-admissions to hospital, and patients who are admitted have a shorter stay. The implications for providing community or home-based services for those living in remote and rural areas are therefore promising.

There is a well established relationship between anxiety and depression and patients with coronary heart disease<sup>45</sup>, which may be due in part to the poor risk factor profiles, including diet, smoking and exercise. Previous studies have shown that cardiac rehabilitation improves symptoms of anxiety and depression in patients<sup>47,48</sup>. The prevalence of depression in CHD patients ranges from 16% to 25%, and from 10% to 29% for anxiety disorders<sup>49</sup>. Anxiety and depression can affect heart rhythms and blood pressure, and can elevate insulin and cholesterol levels and increase smoking, with highly anxious patients at 3-6 times greater risk of MI and sudden death<sup>49</sup>. In the two main home-based rehabilitation programs under review, namely the Heart Manual and the Angina Plan, psychological components are central to the successful rehabilitation of patients.



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

A recent Cochrane Review<sup>50</sup> carried out a full meta-analysis on research of home versus hospital studies. This review found no statistically significant difference between home and hospital rehabilitation for the following outcomes: mortality, cardiac events, exercise capacity, modifiable risk factors, blood pressure, total cholesterol and health related quality of life. This supports findings from the BRUM<sup>23</sup> and Cornwall Heart Attack Rehabilitation Management Study (CHARMS)<sup>27</sup> studies and shows that patients receiving both home- and hospital-based rehabilitation benefit in many ways by completing their rehabilitation. Flint et al<sup>51</sup> have stated that 29% of networks had increased uptake of home options (during the period 2007-2008) within the English Cardiac Networks group. This evidence suggests an improvement in the provision of home rehabilitation as an option. This is promising data because attendance at cardiac rehabilitation remains poor.

At present, home-based cardiac rehabilitation may be offered in some areas as an alternative to hospital-based programs. The lack of standardisation of rehabilitation programs within hospital, community and home settings makes direct comparisons difficult. It is possible where there is a small treatment effect that patients receiving usual care or that have returned to the care of their family physician have attended rehabilitation and exercise classes elsewhere, but in the majority of cases this is not identified. This might explain the variety in outcomes seen when comparing home rehabilitation with usual care and its lack of impact in some studies<sup>26,28,43</sup>. Nevertheless, when home rehabilitation in its many forms has been directly compared with hospital-based programs, there appears to be a consensus that there is no significant difference in outcomes for patients between these two approaches, with both approaches being effective at improving a number of clinical and psychological parameters. However, there is some evidence to suggest that patients receiving home rehabilitation may maintain greater levels of physical activity than those completing hospital-based programs<sup>34,35</sup>. Thus, it appears that home-based rehabilitation can be both safe and effective for those unable to attend a secondary or tertiary care centre. Therefore those receiving home-based care should be at no disadvantage compared with their hospital counterparts. The review of the data suggests that home programs can and should

be offered alongside hospital intervention, instead of as a secondary option. This would support an approach based on patient preference and, indeed, such may help increase the uptake of cardiac rehabilitation which remains dismally poor, especially in those who see distance or lack of time as a major barrier to attendance. There are several studies into the reasons for poor participation rates in  $CR^{12,15,46,50}$  but there is clearly a need for more investigation. Although the distance a patient has to travel to attend cardiac rehabilitation is a well known barrier to attendance, there are other issues relevant to remote and rural patients which need to be further investigated. A high drop-out rate is not unusual for cardiac rehabilitation programs but may limit the generalisability of these results. The interaction between rurality and participation rates has not been established and there is a need for further research in this area.

#### Study limitations

One major limitation with these data is the inconsistency between studies in terms of what was being provided as 'home' or 'community based' cardiac rehabilitation. In the late 1980s and early 1990s the position was similar with respect to hospital-based cardiac rehabilitation programs, where the benefits were known but there were no standard guidelines<sup>52</sup>. Indeed, there appears to be no consensus as to what constitutes 'home rehabilitation' and study interventions ranged from a few telephone calls to a fully comprehensive home-based rehabilitation program, equivalent to what is usually provided in a hospital environment. Another problem with these data was the lack of detail regarding 'usual' or 'standard' care. The majority of studies provided little information on what care these patient groups received. Lack of detail about study design makes it difficult to evaluate the true effect of interventions. Furthermore, cardiac rehabilitation is indicated in several different cardiac patient groups with a range of risks from post myocardial infarction to chronic stable angina, and the timing of recruitment into a cardiac rehabilitation program varied. Thus, mortality outcomes between studies are not directly comparable. The need for clearer guidelines and a more consistent approach is apparent from the broad range of interventions seen in the studies informing this review.

The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy



- Clear guidelines on home-based cardiac rehabilitation are lacking
- Most studies are small and have poorly defined control groups
- There is no consistent difference in outcomes between home and hospital-based cardiac rehabilitation
  - Home cardiac rehabilitation appears safe and effective at improving cardiac risk factors
  - Home cardiac rehabilitation may have longer lasting effects in terms of physical activity maintenance
- Home cardiac rehabilitation may be more acceptable to and convenient for rural patients
- Home cardiac rehabilitation may be more cost-effective for healthcare providers

Figure 2: Home cardiac rehabilitation systematic review key points.

#### **Implications**

The implications of the systematic review key points (Fig2), merit special consideration. The evidence suggests that home-based rehabilitation using resources such as the Heart Manual<sup>18</sup>, can be an acceptable and appropriate alternative to the more traditional hospital-based setting. However, it must be pointed out that not all rural communities are homogenous, and each will have separate needs and requirements. The UK National Health Service (NHS) is moving toward encouraging self care<sup>53</sup> in patients, and this review supports the need and potential benefit to offering patients a choice in their mode of rehabilitation. The role of telehealth in rural communities has an ever-increasing presence and can also be used to expand on the home rehabilitation the patient receives, with potential for specialist input via video conference, or one-to-one discussions with an exercise specialist with regard to progress or similar uses. The increasing use of home rehabilitation as an option<sup>51</sup> protects patients from missing out on vital information and education to help aid recovery from a cardiac event.

Rural-and-Remote-Health

#### Need for further research

There is lack of research covering longer term follow up of patients completing home-based rehabilitation. This information would provide vital knowledge on outcomes such as mortality and physical activity maintenance for those receiving this mode of service delivery. More work is needed on the long-term effectiveness and safety of different modes of home service delivery. This includes home rehabilitation and also for more modern approaches such as 'tele-rehab' or interactive internet-based, self-help programs, which could provide a more flexible option for some patients. These approaches are potentially accessible to many and would offer further choice and flexibility previously not available, particularly for remote and rural residents. Research investigating effectiveness and cost-analysis for these modern approaches to rural care would offer patients the chance to make an informed choice on their mode of rehabilitation. Few data are currently available to inform healthcare providers on attendance issues for rural patients. Expansion of knowledge in this area would allow an insight into the service redesign that may be beneficial in rural areas.

#### Conclusion

Patient groups who are most likely to benefit from the provision of home rehabilitation services vary, and those living in remote and rural locations are likely to be one of those groups. In geographical regions where a considerable proportion of patients live in remote communities, and where the current provision and accessibility of cardiac rehabilitation is inadequate, home-based intervention appears a safe, viable and effective option and offers a convenient means of delivering the information that would be missed by not being able to attend a hospital-based program. Self-help manuals such as the Heart Manual and Angina Plan are not new to cardiac rehabilitation, and minimise the cost to the patient and are accessible to friends and family supporting the patient. The evidence shows that this is an effective

The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

method of rehabilitation, yet few NHS providers offer this type of intervention to their patients as a standard adjunct, or as an alternative to hospital-based care. Home rehabilitation is a safe and effective therapy which could, and possibly should, be offered to all eligible cardiac patients.

#### Acknowledgement

Julie Blair is supported by a grant from Burdett Trust for Nursing.

#### References

1. Clark AM, Hartling L, Vandermeer B, McAlister FA. Metaanalysis: secondary prevention programs for patients with coronary artery disease. *Annals Internal Medicine* 2005; **143**: 659-672.

2. Jolliffe J, Rees K, Taylor RRS, Thompson DR, Oldridge N, Ebrahim S. Exercise-based rehabilitation for coronary heart disease. *Cochrane Database of Systematic Reviews* 2001; Issue 1: Art. No.: CD001800. DOI: 10.1002/14651858.CD001800.

3. Taylor RS, Brown A, Ebrahim S, Jolliffe J, Noorani H, Rees K et al. Exercise-based rehabilitation for patients with coronary heart disease: systematic review and meta-analysis of randomized controlled trials. *American Journal of Medicine* 2004; **116**: 682-692.

4. Thompson DR, Bowman GS, Kitson AL, de Bono DP, Hopkins A. Cardiac rehabilitation in the United Kingdom: guidelines and audit standards. *Heart* 1996; **75:** 89-93.

5. Scottish Intercollegiate Guidelines Network. *Scottish Intercollegiate Guidelines Network cardiac rehabilitation: a national clinical guideline*. Edinburgh: SIGN, 2002.

6. Department of Health. *National Service framework for coronary heart disease*. London: Department of Health, 2000.

7. British Association for Cardiac Rehabilitation. *Standards and core components for cardiac rehabilitation*. British Association of Cardiac Rehabilitation. (Online) 2007. Available: www.bcs.com/ documents/BACR\_Standards.pdf (Accessed 18 January 2011).

8. Thompson DR, Clark AM. Cardiac rehabilitation - into the future. *Heart* 2009; **95:** 1897-1900.

9. Caan W. Most British research and development in primary care arises outside rural areas. *BMJ* 1997; **314**: 1831.

10. Commission for Rural Communities. The implications for health services of the ageing rural population (CRC F05). (Online) 2008. Available: www.ruralcommunities.gov.uk (Accessed 19 April 2010).

11. King G, Farmer J. What older people want: evidence from a study of remote Scottish communities. *Rural and Remote Health* **9**:1166. (Online) 2009. Available: www.rrh.org.au (Accessed 21 March 2011).

12. Cooper AF, Jackson G, Weinman J, Horne R. Factors associated with cardiac rehabilitation attendance: a systematic review of the literature. *Clinical Rehabilitation* 2002; **16**: 541-552.

13. Daly J, Sindone AP, Thompson DR, Hancock K, Chang E, Davidson P. Barriers to participation in and adherence to cardiac rehabilitation programs: a critical literature review. *Progress Cardiovascular Nursing* 2002; **17**: 8-17.

14. Angelis CD, Bunker S, Schoo A. Exploring the barriers and enablers to attendance at rural cardiac rehabilitation programs. *Australian Journal of Rural Health* 2008; **16**: 137-142.

15. Dollard J, Smith J, Thompson DR, Stewart S. Broadening the reach of cardiac rehabilitation to remote and rural Australia. *European Journal of Cardiovascular Nursing* 2004; **3**: 27-42.

16. King K, Humen D, Teo K. Cardiac rehabilitation: the forgotten intervention. *Canadian Journal of Cardiology* 1999; **15**: 979-985



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

17. Bethell HJN, Turner SC, Mullee MA. Cardiac Rehabilitation in the Community: 11 year follow up after a randomised control trial. *Coronary Health Care* 1999; **3**: 183-188.

18. Lewin B, Robertson IH, Cay EL, Irving JB, Campbell M. A self-help post-MI rehabilitation package – the Heart Manual: effects on psychological adjustment, hospitalisation and GP consultation. *Lancet* 1992; **339**: 1036-1040.

19. Lewin RJP, Furze G, Robinson J, Griffith K, Wiseman S, Pye M et al A randomised controlled trial of a self-management plan for patients with newly diagnosed angina. *British Journal General Practice* 2002; **52**: 194-196,199-201.

20. MacLean E, Patience F, Leslie SJ. The Angina Plan: Correcting the misconceptions of patients with coronary heart disease. *British Journal Cardiac Nursing* 2007; **2(8)**:399-403.

21. Oldridge NB, Donner AP, Buck CW, Jones NL, Andrew GM, Parker JO et al Predictors of dropout form cardiac exercise rehabilitation. Ontario Exercise-Heart Collaborative Study. *American Journal of Cardiology* 1983; **51:** 70-74.

22. Denolin H. Rehabilitation and secondary prevention of patients after myocardial infarction. WHO collaborative study. *Advances in Cardiology* 1982; **31**: 107-111.

23. Jolly K, Taylor R, Lip GYH, Greenfield SM, Raftery J, Mant JWF et al The Birmingham Uptake Maximisation Study (BRUM). Home-based compared with hospital-based cardiac rehabilitation in a multi-ethnic population: cost effectiveness and patient adherence. *Health Technology Assessment* 2007; **11(35):** 1-118.

24. Sinclair AJ, Conroy SP, Davies M, Bayer AJ. Post-discharge home-based support for older cardiac patient: a randomised controlled trial. *Age Ageing* 2005; **34**: 338-343.

25. Higgins HC, Hayes RL, McKenna KT. Rehabilitation outcomes following percutaneous coronary interventions (PCI). *Patient Education and Counselling* 2001; **43**: 219-230.

26. Lear SA, Spinelli JJ, Linden W, Brozic A, Kiess M, Frohlich JJ et al The Extensive Lifestyle Management Intervention (ELMI) after cardiac rehabilitation: A 4 year randomised controlled trial. *American Heart Journal* 2006; **152**: 333-339.

27. Dalal HM, Evans PH, Campbell JL, Taylor RS, Watt A, Read KLQ et al Home-based versus hospital based rehabilitation after myocardial infarction: A randomised trial with preference arms – Cornwall Heart Attack Management Study (CHARMS). *International Journal of Cardiology* 2007; **119**: 202-211.

28. Jolly K, Bradley F, Sharp S, Smith H, Thompson S, Kinmonth AL et al Randomised controlled trial of follow up care in general practice of patients with myocardial infarction and angina: final results of Southampton heart integrated care project (SHIP). *BMJ* 1999; **318**: 706-711.

29. Bethell HJN, Mullee MA. A controlled trial of community based coronary rehabilitation. *British Heart Journal* 1990; **64**: 370-375.

30. Canyon S, Meshgin N. Cardiac rehabilitation: reducing hospital readmissions through community based programmes. *Australian Family Physician* 2008; **37:** 575-577.

31. Young W, Rewa G, Goodman SG, Jaglal SB. Evaluation of a community-based inner-city disease management program for post myocardial infarction patients: a randomised controlled trial. *Canadian Medical Association Journal* 2003; **169**: 905-910.

32. Robertson K, Kayhko K, Kekki P. A supportive education home follow up program for post MI patients. *Journal of community Nursing* 2003; **17**: 6.

33. Taylor C, Barr, Miller NH, Smith PM, DeBusk RF. The effect of a home-based, case-managed, multi-factorial risk-reduction program on reducing psychological distress in patients with cardiovascular disease. *Journal of Cardiopulmonary Rehabilitation* 1997; **17**: 157-162.



The International Electronic Journal of Rural and Remote Health Research, Education Practice and Policy

34. Smith KM, Arthur HM, McKelvie RS, Kodis J. Differences in sustainability of exercise and health-related quality of life outcomes following home or hospital-based cardiac rehabilitation. *European Journal Cardiovascular Prevention and Rehabilitation* 2004; **11**: 313-319.

35. Marchionni N, Fattirolli F, Fumagalli S, Oldridge N, Del Lungo F, Morosi L et al Improved exercise tolerance and quality of life with cardiac rehabilitation of older patients after myocardial infarction: results of a randomised controlled trial. *Circulation* 2003; **107**: 2201-2206.

36. Arthur HM, Smith KM, Kodis J, McKelvie R. A controlled trial of hospital versus home based exercise in cardiac patients. *Medicine, Science, Sports and Exercise* 2002; **34**: 1544-1550.

37. Gary RA, Sueta CA, Dougherty M, Rosenberg B, Cheek D, Preisser J et al. Home-based exercise improves functional performance and quality of life in women with diastolic heart failure. *Heart Lung* 2004; **33**: 210-218.

38. Kodis J, Smith KM, Arthur HM, Daniels C, Suskin N, McKelvie RS. Changes in exercise capacity and lipids after clinic versus home-based aerobic training in coronary artery bypass graft surgery patients. *Journal of Cardiopulmonary Rehabilitation* 2001; **21**: 31-36.

39. Carlson JJ, Johnson JA, Franklin BA, VanderLaan P. Program participation, exercise adherence, cardiovascular outcomes, and program cost of traditional versus modified cardiac rehabilitation. *American Journal Cardiology* 2000; **86**:17-23.

40. Oliveira J, Ribeiro F, Gomes H. Effects of a home-based rehabilitation program on the physical activity levels of patients with coronary artery disease. *Journal Cardiopulmonary Rehabilitation Prevention* 2008; **28**: 392-396.

41. Jones MI, Greenfield S, Jolly K. Patients' experience of home and hospital based cardiac rehabilitation: a focus group study. *European Journal Cardiovascular Nursing* 2009; **8**: 9-17.

42. Lacey EA, Musgrave RJ, Freeman JV, Tod AM, Scott P. Psychological morbidity after myocardial infarction in an area of deprivation in the UK: evaluation of a self help package. *European Journal Cardiovascular Nursing* 2004; **3**: 219-224.

43. Frasure-Smith N, Lesperance F, Prince RH, Verrier P, Garber RA, Juneau M et al Randomised Trial of home-based psychosocial nursing intervention for patients recovering from myocardial infarction. *Lancet* 1997; **350**: 473-479.

44. Taylor RS, Watt A, Dalal HM, Evans PH, Campbell JL, Read KL et al Home-based cardiac rehabilitation versus hospital-based rehabilitation: a cost effectiveness analysis. *International Journal of Cardiology* 2007; **119:** 196-201.

45. Bjarnason-Wehrens B, McGee H, Zwisler AD, Piepoli MF, Benzer W, Schmid JP et al. Cardiac rehabilitation in Europe: results from the European Cardiac Rehabilitation Inventory Survey. *European Journal of Cardiovascular Prevention & Rehabilitation* 2010; **17(4):** 410-418

46. Kerins M, McKee G, Bennett K. Contributing factors to patient non-attendance at and non-completion of Phase III cardiac rehabilitation. *European Journal of Cardiovascular Nursing* 2011; **10(1):** 31-36.

47. Glazer K, Emery CF, Frid DJ, Banyasz RE. Psychological predictors of adherence and outcomes among patients in cardiac rehabilitation. *Journal of Cardiopulmonary Rehabilitation* 2002; **22:** 40-46.

48. McGee H, Hevey D, Horgan JH. Psychosocial outcome assessments for use in cardiac rehabilitation service evaluation: a 10-year systematic review. *Social Science Medicine* 1999; **48**: 1373-1393.

49. Serber ER, Todaro JF, Tilkemeir PL, Niaura P. Prevalence and characteristics of multiple psychiatric disorders in cardiac rehabilitation patients. *Journal of Cardiopulmonary Rehabilitation and Prevention* 2009; **29**: 161-168.





T, Taylor RS. Home 52. Thompson DR. Ca

50. Dalal HM, Zawada A, Jolly K, Moxham T, Taylor RS. Home based versus centre based cardiac rehabilitation: Cochrane systematic review and meta-analysis. *BMJ 2010*; **340**: b5631.

51. Flint J, Shahid M, Varghese M. Cardiac rehabilitation: we should all be doing it - Correspondence. *British Journal of Cardiology* 2010; **17(1):** 19.

52. Thompson DR. Cardiac rehabilitation services: the need to develop guidelines. *Quality in Health Care* 1994; **3**:169-172.

53. Department of Health. *Supporting people with long term conditions to self care: a guide to developing local strategies and good practice*. London: DoH, 2006. Available: http://www.dh.gov. uk/assetRoot/04/13/08/68/04130868.pdf

