Randomised trials of secondary prevention programmes in coronary heart disease: systematic review

McAlister F A, Lawson F M, Teo K K, Armstrong P W

Authors' objectives
To determine whether multidisciplinary disease management programmes for patients with coronary heart disease (CHD) improve processes of care and reduce morbidity and mortality.

Searching
The following databases were searched: MEDLINE from 1966-2000; EMBASE from 1980 to 1999; CINAHL from 1982 to 1999; SIGLE from 1980 to 1999; the Cochrane Controlled Trials Register; and the Cochrane Effective Practice and Organisation of Care Register of trials. The textwords and MeSH terms used were: 'case management (exp)', 'comprehensive health care (exp)', 'disease management (exp)', 'health services research (exp)', 'home care services (exp)', 'clinical protocols (exp)', 'patient care planning (exp)', 'quality of health care (exp)', 'rehabilitation', 'nurse led clinics', 'special clinics' and 'myocardial ischemia (exp)'. Studies reported in any language were considered. The bibliographies of the identified studies were searched, and experts were contacted. Where necessary, the original investigators of the included studies were contacted for additional information.

Study selection
Study designs of evaluations included in the review
The inclusion criteria specified randomised controlled trials only, involving at least 50 patients.

Specific interventions included in the review
Studies of disease management programmes were eligible for inclusion in the review. The authors define disease management programmes as 'a combination of patient education, provider use of practice guidelines, appropriate consultation, and supplies of drugs and ancillary services'. The interventions in the included trials were described as: multidisciplinary teams or nurse-led interventions including variously exercise-based rehabilitation, social and psychological support for patients, health education, counselling, stress management, management of risk factors, frequent telephone contact and clinic visits, discharge planning, coordination of home care, and standardised protocols to optimise medications. The duration of the interventions and follow-up ranged from one month to 4 years. Studies were excluded if they were primary prevention or evaluated single modality interventions, e.g. just exercise. The control groups were 'usual care', which was generally undefined.

Participants included in the review
The selection criteria specified patients with CHD, i.e. angina, myocardial infarction or coronary revascularisation. Trials involving patients with multiple diseases were included if the outcomes were reported separately for those with CHD, or CHD patients comprised at least half of the study participants. Two of the studies included participants with congestive heart failure or CHD, while another study included participants with 'heart disease'. The majority of the trials involved patients discharged from hospital but some were recruited from primary care. Studies of in-patients were excluded. The trials included both male and females, with mean ages ranging from 49 to 76 years.

Outcomes assessed in the review
The outcomes to be assessed were all-cause mortality, myocardial infarction and the rates of admission to hospital. In addition, the following outcomes were reported: the impact on risk factors (cholesterol levels, smoking cessation, blood-pressure reduction), use of drugs (antiplatelet agents, beta-blockers, lipid-lowering drugs), quality of life assessed using scales (Beck depression, SF-36, enforced dependency scale), and the functional status or symptom scores.

How were decisions on the relevance of primary studies made?
The authors state that two reviewers independently reviewed all the titles, abstracts and full text for inclusion.
Assessment of study quality
The authors do not state that they assessed quality.

Data extraction
The authors state that two reviewers independently extracted the data using pre-standardised data abstraction forms. Any discrepancies were resolved by consensus. The data extracted included: the number of participants; the patients' characteristics (age ranges and mean ages, diagnosis); location (country) of study; the proportion of males; key components of the intervention; duration of the intervention; and outcomes, i.e. myocardial infarction, all-cause mortality, reduction in smoking, smoking cessation, use of drug therapies, quality of life (effect size), and deterioration in functional status or symptom scores. The authors state that the outcomes were assigned on an intention to treat basis.

Methods of synthesis
How were the studies combined?
The studies were combined by a meta-analysis, using Meta-Analyst software (version 0.998). The risk ratios (RRs) were calculated for the primary outcomes. The studies were combined using the random-effects model of DerSimonian and Laird (see Other Publications of Related Interest no.1) and the Mantel-Haenszel-Peto fixed-effect model. The results from the two approaches were similar, thus, only the fixed-effect results were reported.

To standardise the reporting of the results for non-dichotomous outcomes (e.g. changes in cholesterol), the effect size technique described by Kazis et al. was used (see Other Publications of Related Interest no.2). The effect size was calculated by dividing the absolute difference between the intervention and control arms by the standard deviation in the control arms.

How were differences between studies investigated?
Cochran's Q test was used to assess heterogeneity in each outcome of interest. In addition, the authors conducted sensitivity analyses to assess the impact of quality of study, year of study completion, duration of the intervention and length of follow-up. Attempts were made to assess the impact of individual elements of the interventions, but the small number of trials and poor reporting of specific elements of the interventions meant that this failed to identify any one component that was statistically beneficial.

Results of the review
Twelve studies (10,357 patients, 9,803 with heart disease) were included. Not all the studies reported all outcomes.

Reinfarction rate: none of the 7 trials reporting this outcome detected any significant difference between the intervention and control groups; the summary RR was 0.94 (95% confidence interval, CI: 0.80, 1.10).

All-cause mortality: only one of the 10 studies reported a significant survival benefit of the intervention; the summary RR was 0.91 (95% CI: 0.79, 1.04).

Rate of admission to hospital: 2 of the 6 trials reporting admission rates found a significant difference; the summary RR was 0.84 (95% CI: 0.76, 0.94).

Risk factors: 5 out of 7 trials reporting changes in risk factors showed significant improvement in the treatment group, although the effect sizes were generally small to moderate.

Use of drugs: 5 out of 7 trials showed a significantly increased use of at least one of the prescription drugs in the treatment groups. The summary RR was 2.14 (95% CI: 1.92, 2.38) for lipid-lowering agents, 1.19 (95% CI: 1.07, 1.32) for beta-blockers, and 1.07 (95% CI: 1.03, 1.11) for antiplatelet agents.

Five out of 8 trials evaluating quality of life or functional status showed better scores in the treatment group, although these were generally small.

The sensitivity analyses showed that the year of study completion, duration of intervention and length of follow-up had
no effect on the observed results. Analysis of the effect of the different components of treatment failed to detect any one statistically beneficial element, although there was a trend towards greater survival in programmes that included structured exercise: RR 0.87 (95% CI: 0.71, 1.05) versus 0.94 (95% CI: 0.78, 1.13).

Cost information
The authors state that three of the studies described costs, two reported that their intervention was cost-saving, but none performed a cost-effectiveness analysis.

Authors’ conclusions
Disease management programmes improve process of care (risk factor profiles, prescription of proved efficacious drugs), reduce admissions to hospital, and enhance quality of life or functional status in patients with CHD. The programmes’ impact on survival and recurrent infarctions, their cost-effectiveness and the optimal mix of components, remain uncertain.

CRD commentary
This paper was clearly written and it provided a good description of the methods used in the review. The literature sources searched were comprehensive. The authors used a broad definition of disease management programmes. However, the inclusion criteria for these interventions were not defined clearly, and this makes it difficult to identify how these programmes differ from studies of other comprehensive cardiac rehabilitation programmes. The information about the components of the disease management programmes (and of the control treatments) in the individual studies was limited. This, and the acknowledged highly selected populations in the studies, means that it is difficult to generalise from the results. Other details of the primary studies were well presented. The included studies were not assessed for quality and, given the nature of the intervention, it is probable that none were blinded. The meta-analyses would seem to have been appropriate. However, the results of the heterogeneity tests were not reported. A sensitivity analysis that excluded the three trials of participants with diagnoses other than 'CHD' would have been interesting. The review included a range of disease management programmes, and it is difficult to identify from this analysis which programmes might offer the most benefit.

Overall, and bearing the above comments in mind, the authors’ conclusions would seem to be supported by the results presented.

Implications of the review for practice and research
Practice: The authors state that the programmes’ impact on survival and recurrent infarctions, their cost-effectiveness and the optimal mix of components, remain uncertain.

Research: The authors imply that further research is needed to determine the optimal mix of interventions in these programmes, their frequency, duration and cost-effectiveness.

Funding
F A McAlister is a population health investigator of the Alberta Heritage Foundation for Medical Research.

Bibliographic details

PubMedID
11679383

Original Paper URL
Other publications of related interest

These additional published commentaries may also be of interest. Micevski V. Review: multidisciplinary disease management programmes do not reduce death or recurrent myocardial infarction but reduce admission to hospital. Evid Based Nurs 2002;5:54. Lancaster T, Moher M. Review: multidisciplinary coronary heart disease management programmes improve the process of care and reduce hospital admissions. Evid Based Med 2002;7:62.

Indexing Status
Subject indexing assigned by NLM

MeSH
Adrenergic beta-Antagonists /therapeutic use; Coronary Disease /mortality /prevention & control; Cost-Benefit Analysis; Disease Management; Hospitalization; Humans; Hypolipidemic Agents /therapeutic use; Platelet Aggregation Inhibitors /therapeutic use; Quality of Life; Randomized Controlled Trials as Topic; Recurrence; Risk; Treatment Outcome

AccessionNumber
12001008403

Date bibliographic record published
28/02/2003

Date abstract record published
28/02/2003

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.